Medication Safety Committee Meeting

March 4, 2020 10 am - 2 pm

California Hospital Association

1215 K Street

Suite 800, Boardroom

Sacramento, CA, 95814

Dial: 800-882-3610 Passcode: 4206832#

Meeting Book - Medication Safety Committee Meeting

Medication Safety Committee Meeting Agenda - March 4, 2020

2:00 IX. ADJOURNMENT
Hanni

X. NEXT MEETING

Wednesday, May 27, 2020

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: March 4, 2020

TO: Medication Safety Committee Members

FROM: Dietmar Grellmann, Senior Vice President, Policy
BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: Member Session/Strategy Development

SUMMARY

To align our committee more directly with CHA 2020 policy and advocacy priorities, we would like to review the 2020 CHA priorities, and the mission of the CHA Medication Safety Committee to develop a specific detailed strategy that includes results-oriented activities and deliverables. In review, CHA seeks to develop consensus and establish public policy and advocacy priorities to serve hospitals and health systems. The present CHA Medication Safety Committee mission is to advise CHA on key policy and advocacy issues specific to pharmacy and medication safety. To move to our 2020 goal, we would like to expand upon our present mission to include specific aligned actions that produce deliverables.

The attached power point slides outline the 2020 public policy priorities as identified from specific regional CEO's, along with top priority issues identified by the CHA policy and advocacy leadership. In summary, the policy priorities are:

- Seismic
- Behavioral Health
- Affordability
    - Coverage for all
    - Equitable Access
    - Improved Value

In addition, the Governor has requested the state move forward on an" Office of Health Care Affordability", to address the surmounting health care costs across the state. Four states across the country have used advisory boards to contain and control health care spending in their states. The state assembly is holding an informational hearing and we will learn more about next steps in the Governor's cost containment considerations for California.

DISCUSSION

1. Reviewing the CEO survey priorities, and CHA priorities, and our overall pharmacy and medication safety issues, how can we more closely align?
2. How do pharmacists contribute to value and affordability in hospitals?
3. What activities do pharmacists do to address rising costs?

BJB:br

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: March 4, 2020

TO: Medication Safety Committee Members

FROM: BJ Bartleson, RN, MS, NEA-BC, VP Nursing and Clinical Services

SUBJECT: Pharmacist's Role in Health Care Affordability

SUMMARY

Governor Newsom is developing an Office of Health Care Affordability to assess and develop health cost containment measures. Attached are several CHCF articles on spending trends and waste in our state health care system, along with a brief relative to how four other states used advisory groups to help contain health care spending. Assembly Committee Hearing feedback from 2/25/20 will be offered for discussion during this meeting (see attachment, Informational Hearing Agenda).

The CHCF article describes six contributors to wasteful spending. 1) overtreatment, 2) failures of care delivery and inadequate prevention, 4) failures at care coordination, 5) administrative complexity, and 6) pricing and market inefficiencies.

CHA is exploring multiple member stakeholders to understand how we are positively affecting health care affordability.

DISCUSSION

1. How do pharmacists provide value and contribute to cost avoidance activities and or other activities that improve cost containment?
2. Do each of you have examples of cost avoidance projects, activities that you are involved in that we could combine to show cost avoidance and or value across the state?
3. Does the Medication reconciliation research work from SB 1254 have cost implications we could make visible relative to pharmacists' contributions?

Attachments: Informational Hearing
Getting to Affordability: Spending Trends and Waste in California's Health Care System
Commissioning Change: How Four States Use Advisory Boards to Contain Health Spending

BJB:br

Assembly
California Legislature

ASSEMBLY COMMITTEE ON HEALTH
JIM WOOD, CHAIR
ASSEMBLYMEMBER, SECOND DISTRICT

Informational Hearing

Cost Containment: Considerations for California

February 25, 2020
9:00 AM – 12:00 PM
State Capitol, Room 4202

AGENDA

I. Opening Remarks: Chair and other Members

II. Overview of Health Care Costs in California
- Larry Levitt, MPP, *Executive Vice President for Health Policy, Kaiser Family Foundation*

III. Trends and Approaches to Health Care Industry Consolidation
- Jaime King, J.D., PhD, *Associate Dean and Bion M. Gregory Chair in Business Law, University of California Hastings College of the Law*

IV. Cost Containment Commissions: State Models

A. Overview
- Glenn Melnick, PhD, *Blue Cross of California Chair in Health Care Finance, USC Price School of Public Policy*

B. Massachusetts Health Policy Commission
- David Seltz, *Executive Director, Massachusetts Health Policy Commission*

C. Oregon Health Authority
- Jeremy Vandehey, J.D., *Director, Health Policy and Analytics Division, Oregon Health Authority*

D. Other state models
- Glenn Melnick

V. Office of Health Care Affordability
- Mark Ghaly, M.D., M.P.H., *Secretary, California Health and Human Services Agency*

VI. All-payer claims databases & California Health Care Payments Database
- Cheryl Damberg, PhD, *Chair in Health Care Policy and Principal Senior Researcher, RAND Corporation*

VII. Other Cost Containment Considerations and Approaches
- Christine Eibner, PhD, *Director, Payment, Cost, and Coverage Program; Director, RAND Corporation*

VIII. Public Comment

CHCF

Getting to Affordability:
Spending Trends and Waste in California's Health Care System

JANUARY 2020

AUTHORS
Christine Eibner, Christopher Whaley, Kandice Kapinos, Nicholas Broten, J. Luke Irwin, Serafina Lanna, Mary Vaiana, and Erin Duffy, RAND Corporation

Contents

About the Authors

Christine Eibner, PhD, is a senior economist and the Paul O'Neill Alcoa Chair in Policy Analysis at RAND Corporation. Also from RAND are Christopher Whaley, PhD, policy researcher; Kandice Kapinos, PhD, senior economist; Nicholas Broten, MS, assistant policy researcher; J. Luke Irwin, MPH, assistant policy researcher; Mary Vaiana, PhD, senior communications analyst; and Erin Duffy, PhD, adjunct policy researcher. Serafina Lanna is a former research assistant at RAND.

This work was conducted independently by RAND Corporation, a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier, and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest.

About the Foundation

The California Health Care Foundation is dedicated to advancing meaningful, measurable improvements in the way the health care delivery system provides care to the people of California, particularly those with low incomes and those whose needs are not well served by the status quo. We work to ensure that people have access to the care they need, when they need it, at a price they can afford.

CHCF informs policymakers and industry leaders, invests in ideas and innovations, and connects with changemakers to create a more responsive, patient-centered health care system.

For more information, visit www.chcf.org.

Introduction

While California has made impressive strides in increasing the number of residents who have health insurance coverage — and proposals for reaching the remaining uninsured continue to be debated at the state and federal level — health care is still far too expensive for the three million Californians who lack coverage and the 37 million who do not. The average cost of a family health insurance plan in California is nearly $20,000 per year, almost one-third of median family income in the state. Premiums for the average family health plan in the employer market in California have increased 133% since 2002, vastly outpacing inflation. The average deductible facing a California family now exceeds $3,000, while the average copay for a physician office visit is nearly $25.[1]

Californians are desperate for relief from these costs. In a 2018 statewide survey, more residents were extremely or very worried about paying for health care than those worried about paying for housing, transportation, or utilities.[2] This fear at least partially reflects Californians' direct experience. About one out of five Californians reported problems paying medical bills for themselves or a family member in the past year, leading them to cut back on basic household spending, use up all of their savings, or delay or forgo medical treatments or prescription drugs.[3] Nearly half experienced some type of cost-related access problem for themselves or a member of their family.[4] Part I of this report further explores how health care costs are affecting the state's residents and forcing state officials to make unnecessary trade-offs.

Part II of this report describes sources of health insurance coverage in the state, spending by payer, and trends in spending over time. Individuals with employer-sponsored insurance are the largest segment of the population, and they account for the largest percentage of health spending in the state. Both inflation-adjusted premiums and deductibles for employer-sponsored insurance increased substantially from 2000 to 2017, with worker contributions to health care more than tripling at businesses with fewer than 25 workers. Office-based visits, inpatient hospital stays, and prescription drugs drive much of health care spending across market segments in California.

There is nothing inherently wrong with rapid growth or high absolute levels of health care spending if the increased expenditure expands coverage or leads to improved care. However, Part III uncovers a troubling pattern in the state: Prices for the same medical treatments vary widely across California, even though these differences do not necessarily reflect higher-quality care. Significant evidence shows that health spending could be reduced without reducing access or undermining quality.

Part IV explores six areas of focus for understanding cost containment approaches targeting unnecessary spending across the state's health care system: (1) overtreatment, (2) failures of care delivery and inadequate prevention, (3) failures of care coordination, (4) administrative complexity, (5) pricing and market inefficiencies, and (6) fraud and abuse. These areas suggest significant opportunities to reduce health spending without adversely affecting patient health outcomes. In 2010, the Institute of Medicine (now the National Academy of Medicine) estimated that almost one-third of the nation's health care spending was wasteful and unnecessary. Shrank et al. updated the IOM estimates using more recent data and found that between 20% and 25% of national health spending can be attributed to waste.[5] Assuming that California has a similar proportion of unnecessary spending, we estimate that the state could save between $58 and $73 billion per year by eliminating unnecessary spending.

Crucial to any cost containment effort is a detailed understanding of what costs are being reduced, where they are coming from, and who has the potential to capture the savings. In this report we focus on the landscape of health care spending and a framework for understanding cost containment approaches in California. The financial impact of a wide range of policy proposals aimed at reducing health care spending will be the subject of a second, follow-up report in this series.

I. Why Health Care Costs Matter

The vigorous public debate often swirling around health care policies may at times obscure the influence that health care costs have on the well-being of the population. To truly understand the importance of lowering the rapid growth of health care spending, it is illuminating to reflect on how citizens themselves are affected by health care costs.

Health care costs and access to quality care are very much on the minds of California residents. In late 2018, the Kaiser Family Foundation and the California Health Care Foundation conducted a representative survey of the state's residents to gauge their views on the health policy priorities facing the state, as well as their experiences in the health care system.[6] Among respondents, making health care affordable was a top priority. About 45% called affordability extremely important, second only to improving public education. When asked specifically about health care, Californians said their highest priorities were ensuring that people with mental health problems could get treatment, increasing access to coverage, and lowering the cost of health care.

Survey respondents' concerns about health care costs appeared to stem from their own experiences. As indicated above, about one out of five Californians reported problems paying medical bills for themselves or a family member in the past year. This number rises to nearly a third of Californians with debilitating medical conditions, those on Medi-Cal or without health insurance, and those with incomes below 200% of the federal poverty level. Residents, especially those without health insurance, reported concerns that they could not pay unexpected medical bills. Some residents who struggled to pay medical bills reported cutting spending on basic household items, putting off vacations or major purchases, and using up all of their savings.

Health care costs caused some Californians to delay or forgo medical treatments or prescription drugs. More than two out of five respondents said they or another family member in their household postponed or skipped care in the past year due to cost, including dental appointments and medical tests (Figure 1). Some didn't fill prescriptions or skipped doses. Californians with lower incomes, those who lack health insurance, and Black and Latino residents were more likely than their white or Asian American counterparts to postpone or forgo care because they feared they would not be able to afford it.

For the 2019–2020 budget year, California allocated $67 billion in total state funds to health and human services, $42 billion of which came from the state general fund.[7] Allocations for health and human services accounted for 28% of all general fund expenditures,

Figure 1. Two Out of Five Californians Postponed or Skipped Getting Health Care Due to Cost

Source: KFF/CHCF California Health Policy Survey (November 12 to December 27, 2018).

up from 25% in the 2018–2019 budget year. Concerns about waste in the system raise the possibility that other public policy priorities like education or housing may be shortchanged at the expense of low-value health care. As former Centers for Medicare & Medicaid Services (CMS) Administrator Donald Berwick discussed in a recent editorial, the degree of wasteful spending in our health system raises the possibility that "schools, small businesses, road builders, bridge builders, scientists, individuals with low income, middle-class people, would-be entrepreneurs, and communities as a whole could make much, much better use of that money."[8]

II. A Snapshot of Health Spending Trends in California

Expenditures on personal health care for Californians totaled $292 billion in 2014, according to CMS.[9] California accounts for roughly 10% of total health spending in the nation.[10]

Individuals with employer-sponsored insurance (ESI) account for the largest portion of both the population and health spending in the state (see Table 1). Inflation-adjusted premiums and deductibles for ESI both increased substantially since 2000, and large increases affected small and large firms alike. At approximately $11,900 per year, Medicare beneficiaries have per-capita health spending that is roughly twice as high as that of other Californians. Spending by Californians without health insurance now accounts for only about 2% of total spending on health care.

Per-capita health spending in the state has grown steadily over time. Those with private health insurance coverage have faced the highest growth rates — about 4% per year. Office-based visits, inpatient hospital stays, and prescription drugs disproportionately fuel increases in health spending in California. With an average annual growth rate of more than 7%, prescription drug spending has far outpaced inflation.

This section uses data from the Medical Expenditure Panel Survey Household Component (MEPS-HC), conducted by the Agency for Healthcare Research and Quality (AHRQ), to explore these and other health spending trends in California from 2000 through 2016.[11] (More details about the report's methodology are in Appendix A.) The remainder of this section presents a detailed analysis of the 2000–2016 MEPS data, including health spending by insurance type, site of service, and employer size.[12]

Table 1. Population Size and Health Spending in California, by Insurance Type, in 2016 Dollars

MARKET SEGMENT	POPULATION SIZE (MILLIONS)	TOTAL SPENDING (BILLIONS)	AVERAGE SPENDING	PERCENTAGE OF POPULATION	PERCENTAGE OF SPENDING
Employer	17.3	$79.5	$4,600	43%	37%
Medicare	4.7	$55.8	$11,900	12%	26%
Medi-Cal	10.6	$56.4	$5,300	26%	27%
Non-group	3.3	$11.5	$3,500	8%	5%
Other	1.5	$5.8	$3,900	4%	3%
Uninsured	2.6	$3.6	$1,400	7%	2%
Totals	**40**	**$213**	**$5,300**	**100%**	**100%**

Note: Totals may not sum due to rounding.

Source: Authors' calculations based on MEPS-HC.

Health Spending by Insurance Type

Considering the wide variety of funding sources in health care is important when assessing the impact of programs on specific populations or groups. In California, with its highly diverse population, this is especially relevant.

Table 1 describes the size of health spending according to the primary source of insurance coverage for a given year. Because the team assigned each individual in the data to a primary source of health insurance, some segments of the market may be assigned lower levels of coverage than estimates that allow for multiple sources of coverage.

Californians with employer-sponsored insurance are the largest group in the market, with 17.3 million enrollees. With average per-capita health spending of $4,600, the ESI population accounts for 37% of health spending in California, as well as 43% of the population.

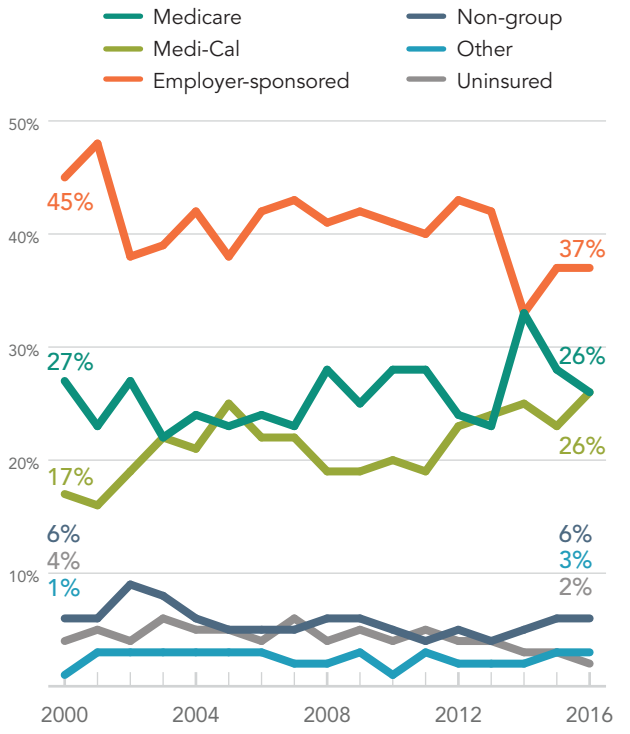
The next-largest group, those with Medi-Cal[13] as their primary source of coverage, accounts for 26% of the population and 27% of health spending. Medi-Cal is funded by state, local, and federal sources.[14] The federal government funds approximately 63% of Medi-Cal expenditures. Nonfederal sources, including California counties and municipalities, provide approximately 16% of Medi-Cal funding, and the remaining 21% comes from the California general fund.[15]

Medicare beneficiaries account for just under 12% of the California population, but they have the highest per-capita health spending ($11,900) and account for 26% of spending on health care. Individuals with non-group coverage (including those who receive coverage through Covered California or other sources of private, individual market insurance) and individuals with miscellaneous other forms of insurance (such as the military's TRICARE program) each have slightly less than $4,000 in health spending per year. The uninsured population accounts for roughly 7% of the California population and 2% of spending. Uninsured Californians spend an average of slightly less than $1,400 on health care per year, the smallest amount of any market segment.

As shown in Figure 2, the share of spending for each insurance type has changed over time.[16] While enrollees in employer-sponsored insurance account for the largest share of health spending, this share declined from 45% to 37% from 2000 through 2016. Medicare spending remained stable since 2000, while the share of California health care spending from patients with Medi-Cal as their source of primary coverage increased from 17% in 2000 to nearly 27% in 2016.

In 2000, the uninsured population accounted for 4% of California health care spending. This share peaked at 6% in 2007 but decreased to 2% in 2016. The most notable declines occurred in 2011, when California began an early expansion of Medi-Cal under the Affordable Care Act (ACA), and in 2014, when the

Figure 2. Share of Annual Health Spending, by Insurance Type, California, 2000–16



Source: Authors' calculations based on data from the MEPS-HC.

ACA's health insurance expansions through Covered California took effect. Spending for those with non-group private insurance and other forms of insurance (such as TRICARE) remained stable over this period.

Figure 3 presents these results in terms of inflation-adjusted per-capita health spending from 2000 through 2016. Unlike the data shown in Table 1, the data in Figure 3 are adjusted to account for variation in spending over time due to extreme outliers (people with spending in the top 1% of the distribution), which could be spurious. As a result, the 2016 estimates reported in Figure 3 (and other trend graphs) differ somewhat from the static estimates presented in Table 1. In each year, mean per-capita spending was highest for Medicare beneficiaries. Over the 2000–2016 time period, average inflation-adjusted per-capita spending for California Medicare beneficiaries increased from $7,700 to $11,000 (after adjustments for outlier spenders), an average annual growth rate of nearly 3%. Medi-Cal patients had the next highest per-capita health spending, although per-capita Medi-Cal spending increased by only about 2% per year during this period. Per-capita spending for the employer-sponsored population increased by just under 4% per year.

These spending differences are reflected in out-of-pocket health spending among patients in different types of insurance plans (see Figure 4). Medicare beneficiaries consistently have the highest out-of-pocket payments. However, after peaking in 2004, Medicare out-of-pocket payments have declined over time. This decrease may be due to the 2006 expansion of Medicare benefits to include prescription drug coverage through Medicare Part D. Out-of-pocket payments also have declined for uninsured Californians and for those with Medi-Cal (who have seen a 28% decrease in inflation-adjusted out-of-pocket patient spending).

In contrast, from 2000 through 2016, annual out-of-pocket patient spending increased by almost 36% for those with employer-sponsored coverage, an average annual increase of 2% per year. Of note, this increase in out-of-pocket spending is below the average annual growth rate of per-capita spending among those with

Figure 3. Mean Per-Capita Per-Enrollee Annual Health Spending, by Insurance Type, California, 2000–16

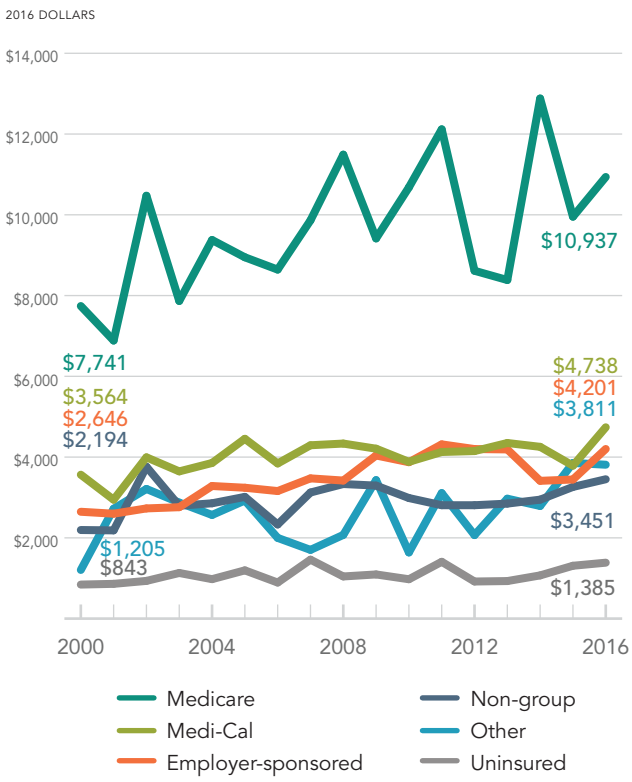
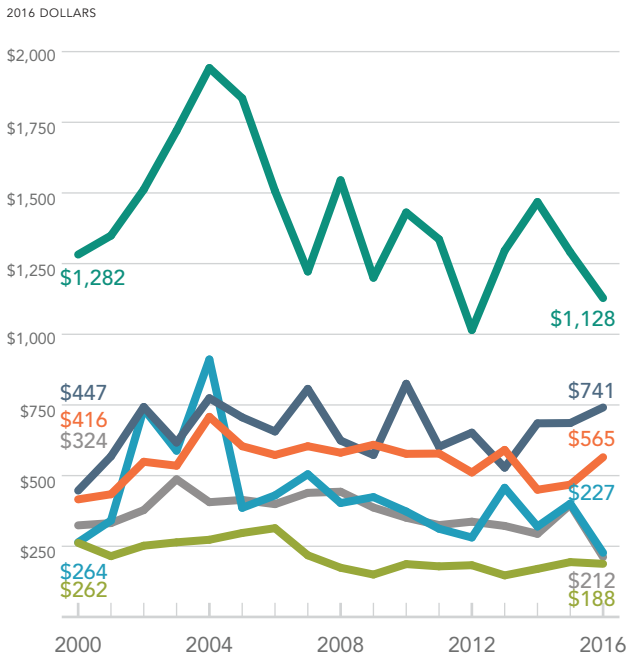


Figure 4. Mean Annual Patient Out-of-Pocket Payments, by Insurance Type, California, 2000–16



Source (Figures 3 and 4): Authors' calculations based on data from the MEPS-HC.

employer-sponsored coverage (just under 4%; see Figure 3). For those with private, individual market coverage rather than coverage from an employer, out-of-pocket payments increased by 66% from 2000 through 2016, an average annual growth rate of around 4%. These increases translate into cumulative increases in average spending from 2000 to 2016 of $149 for Californians with employer-sponsored insurance and $294 for those with non-group commercial insurance, after adjusting for outlier spenders.

Health Spending by Site of Service

Table 2 presents health spending by site of service. At nearly $60 billion per year for each, inpatient hospital and office-based medical provider services account for the largest shares of annual spending, approximately 28% each in 2016. Californians spent $45.6 billion on prescription drugs in 2016, which accounted for about 21% of spending that year.

Table 2. Health Spending, by Site of Service, 2016

SITE OF SERVICE	AMOUNT (BILLIONS)	SHARE OF TOTAL	AVERAGE PER-CAPITA
Office-based	$59.2	28%	$1,500
Inpatient	$59.1	28%	$1,500
Prescription drugs	$45.6	21%	$1,100
Dental	$16.9	8%	$400
Other	$14.7	7%	$400
Hospital outpatient	$9.4	4%	$200
Emergency	$7.9	4%	$200
Totals	**$213**	**100%**	**$5,300**

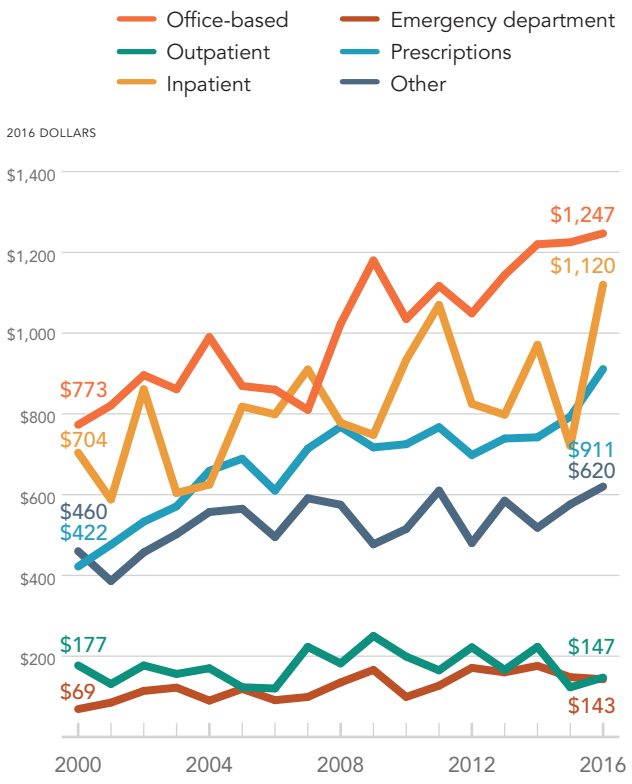
Note: Totals may not sum due to rounding.

Source: Authors' calculations based on MEPS-HC.

Figure 5 shows changes in spending by site of service, with adjustments for outlier spenders. From 2000 through 2016, the share of health spending attributed to each site of care increased for all but outpatient hospital services. Per-capita spending on office-based medical provider services increased by almost 4% per year, as did spending on inpatient hospital services. For prescription drugs, the growth rate was even larger, increasing by an average annual rate of about 7%.

These results have important implications for potential health policy options. Office-based medical provider services and inpatient visits account for the largest shares of health spending in California. Policies that address use of these services may create large potential savings opportunities. Likewise, prescription drug costs have grown more rapidly than growth in any other cost area studied. Policies that address rising drug prices can help reduce this growing cost burden.

Figure 5. Per-Person Annual Health Spending, by Site of Service, California, 2000–16



Source: Authors' calculations based on data from the MEPS-HC.

Employer-Sponsored Insurance Spending by Business Size

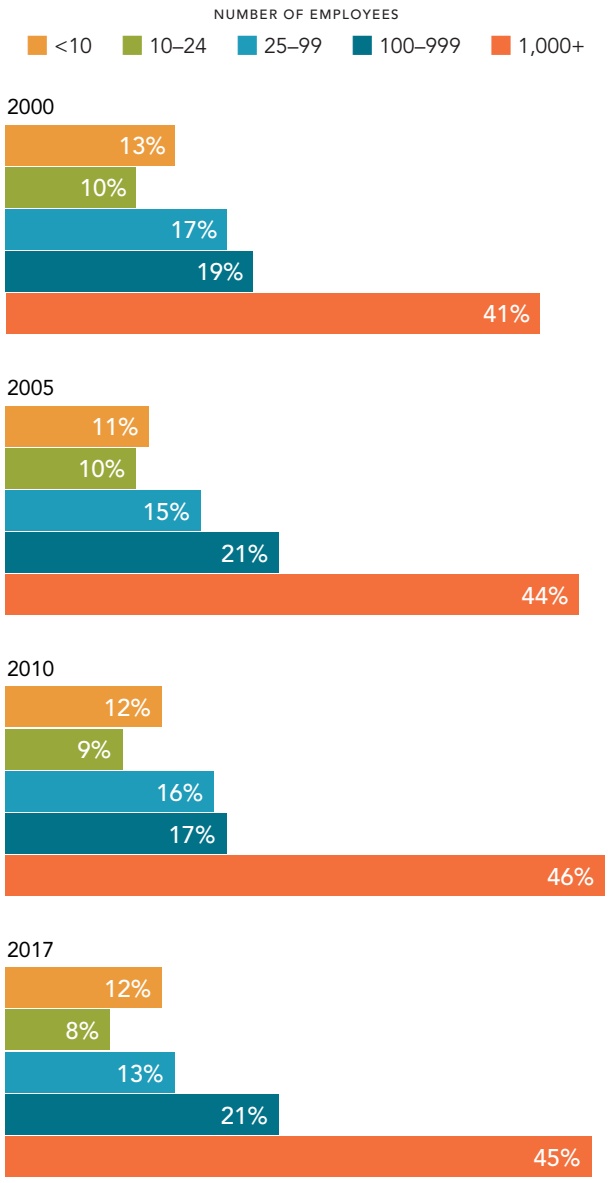
Individuals with employer-sponsored insurance (ESI) make up the largest population segment in California. To better understand this population, the research team also examined health spending for different types of ESI. Analysis of the California ESI market used MEPS Insurance Component (MEPS-IC) data specific to California employers.[17]

ESI plans have two options: (1) self-funding, in which the employer is responsible for health care costs but pays the insurer an administrative fee; or (2) remaining fully insured, in which the employer contracts with an insurer to provide health insurance benefits. Nationwide, about 60% of people with ESI were enrolled in self-funded health plans in 2017; in California, however, only about 46% of private-sector ESI enrollees were in self-funded plans.[18] The lower enrollment in self-funded plans in California may reflect the state's high level of HMO penetration, and also the dominance of Kaiser Permanente, which offers only fully insured plans. Self-funded insurance is more common at large firms than at small ones. According to the MEPS-IC data, 70% of California health insurance enrollees at firms with 1,000 or more workers were in self-funded plans, compared with only 12% of enrollees at firms with fewer than 50 workers.

In the figures below, the team used the MEPS-IC data to examine trends in both coverage and spending for Californians with ESI, breaking down the numbers according to firm size. The team examined ESI enrollment, the average premium for a single enrollee (that is, for a plan that covers only a single person and does not cover dependents), and the average deductible for a single enrollee.

Figure 6 presents the share of the total employer-sponsored health insurance population by firm size. Employees not eligible for health insurance are excluded from these percentages. Californians who work for a firm with 1,000 or more employees account for the largest portion of the ESI population, and this share has grown over time. From 2000 through 2017,

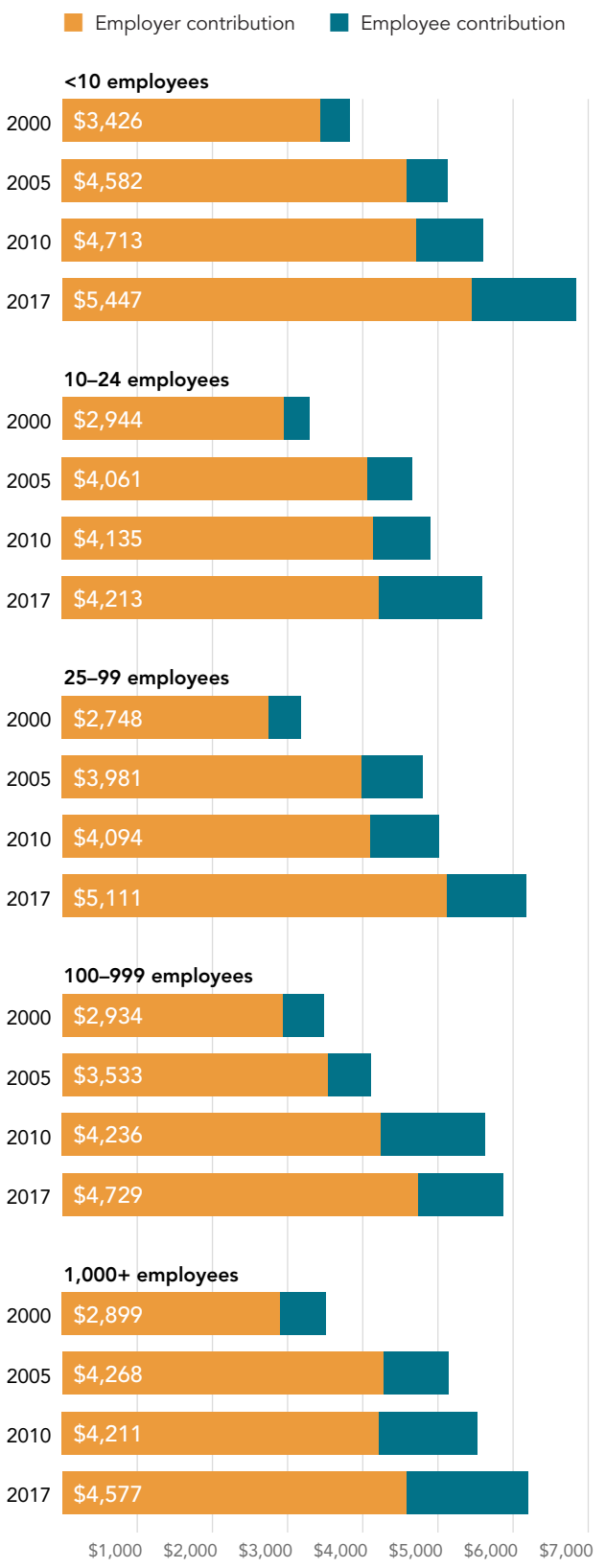
Figure 6. Share of the Employer-Sponsored Insurance Population, by Firm Size, California, 2000–17, Selected Years



Note: Totals may not sum due to rounding.

Source: Authors' calculations based on data from the MEPS-IC.

Figure 7. Employers' Share of Premium, by Firm Size, California, 2000–17, Selected Years



the share of the ESI population that works for a firm with 1,000 or more employees increased from 41% to 45%; while the share of the ESI population that works for a firm with 100 to 999 employees increased from 19% to 21%. The share of enrollees who worked at firms with fewer than 100 workers declined over the same time period.

Figure 7 shows differences in average total premiums in California for a single enrollee (that is, an enrollee in a plan that covers only a single person and does not cover dependents) by firm size. Premiums include employer and employee contributions. In 2017, the average total single-enrollee premium in California was nearly $7,000 for firms with fewer than 10 workers and roughly $6,000 for firms of other sizes. Although the smallest firms (those with fewer than 10 workers) consistently have the highest premiums, a consistent relationship between premiums and firm size does not appear in the data.

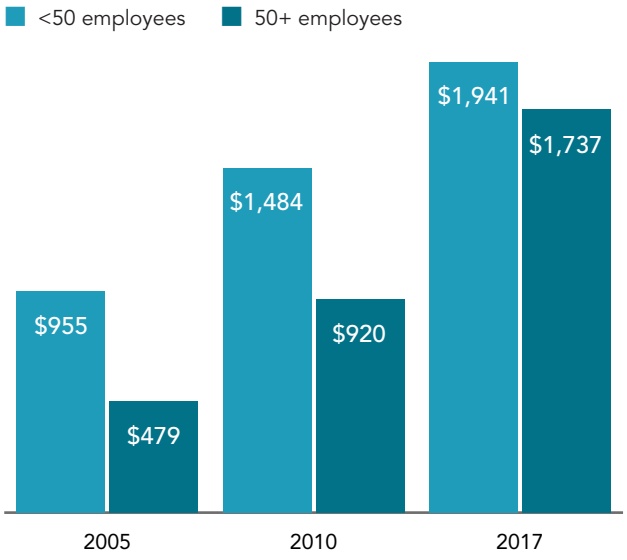
Worker contributions more than doubled from 2000 through 2017. Firms with fewer than 25 workers faced the largest increases in worker contributions, which more than tripled over the time period studied.

Since 2000, average total premiums increased by between 68% and 94% in absolute terms, with the largest increases at firms with 25 to 99 workers. Worker contributions more than doubled from 2000 through 2017. Firms with fewer than 25 workers faced the largest increases in worker contributions, which more than tripled over the time period studied.

Source (Figure 7): Authors' calculations based on data from the MEPS-IC.

Figure 8 examines trends in annual deductibles for ESIs. Deductibles represent the amount that patients are required to pay "out of pocket" before insurance coverage begins.[19] Although employees of smaller firms face consistently higher average deductibles than those of larger firms, the gap has narrowed over time. For example, while deductibles approximately doubled for firms with fewer than 50 employees between 2005 and 2017, deductibles for larger firms nearly quadrupled over the same time period.

Figure 8. Average Individual Employer-Sponsored Deductible, California, 2000–17, Selected Years



Source: Authors' calculations based on data from the MEPS-IC.

III. Disparities That Signal Wasteful Spending

As the preceding sections demonstrate, rapidly rising health care costs have a dramatic impact on Californians' lives, and these cost increases are not spread equally across the various types of insurance, sites of service, and sizes of businesses. Increases in health care costs are also not spread equally across the state. In addition, prices for the same medical treatment vary widely across California, and these differences do not necessarily reflect differences in the quality of care.

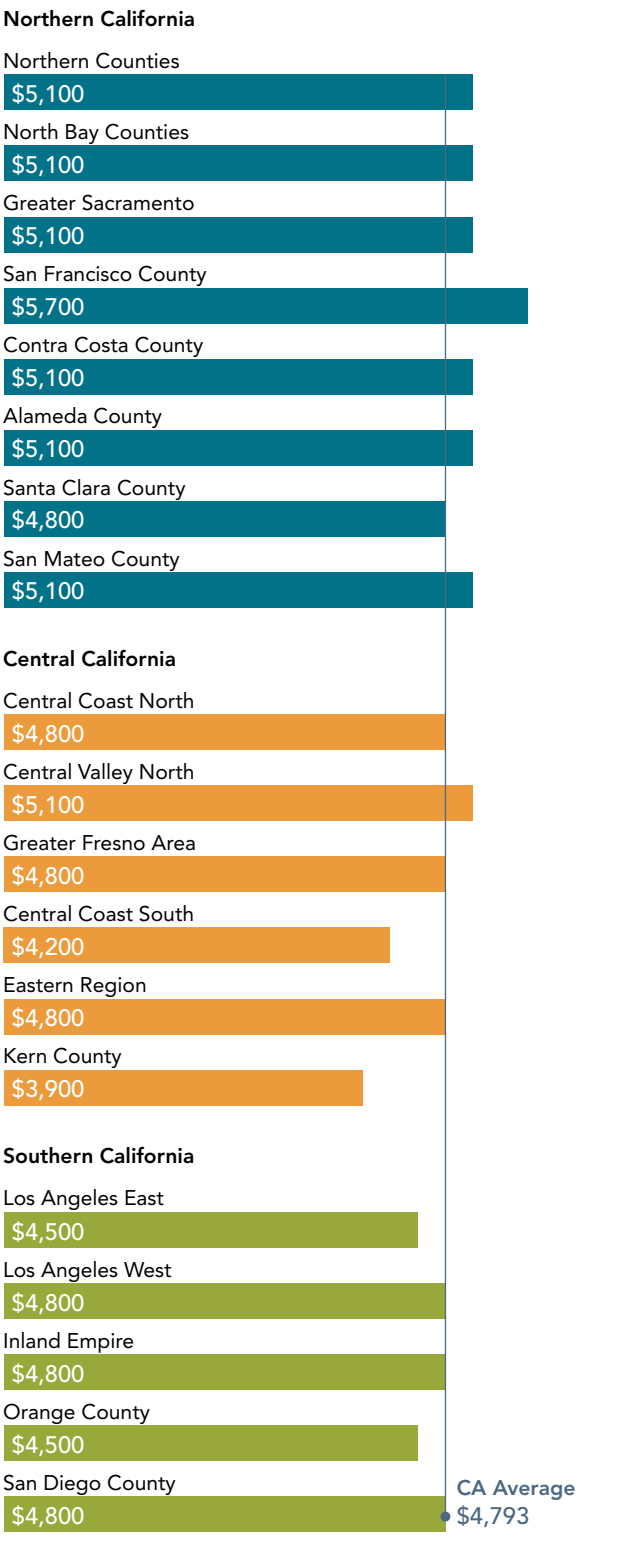
For example, the Integrated Healthcare Association estimated that if all Californians with commercial and Medicare insurance received care at the same cost as in San Diego — one of the least expensive major metropolitan areas in which to receive health care, and a city with high-quality care — total costs to the state would decrease by an estimated $11 billion annually.[20]

This section provides an overview of the considerable price and quality disparities across California, using publicly available sources. The disparities outlined below signal enormous areas of wasted spending, and they represent clear opportunities to reduce health care spending without compromising quality and outcomes.

Price Disparities by County and Region in California

According to the California Regional Health Care Cost & Quality Atlas (the Atlas) — a resource that analyzes clinical quality, hospital use, and the cost of care for three-fourths of the state's population — prices and quality vary widely across the state.[21,22] To illustrate the range of variation, Figure 9 provides a snapshot of the range of average total risk-adjusted costs of care per member per year for the commercially insured across the state.[23]

Figure 9. Average Total Cost of Care,* Commercially Insured Californians, by Region, 2017



*Geography and ACG risk adjusted.

Source: Integrated Healthcare Association. California Regional Health Care Cost & Quality Atlas: Total Cost of Care – Geography and ACG Risk Adjusted – Commercial. 2017. Accessed January 7, 2020.

Average annual costs range from a high of $5,700 in San Francisco County to a low of $3,900 in Kern County. Other components of the total cost of care show similar magnitudes of variation across the state. For example, pharmacy costs range from an average of $650 per member per year in several locations, including Alameda County, Central Valley North, Kern County, and much of the southeastern part of the state to $1,100 per member per year in San Francisco.

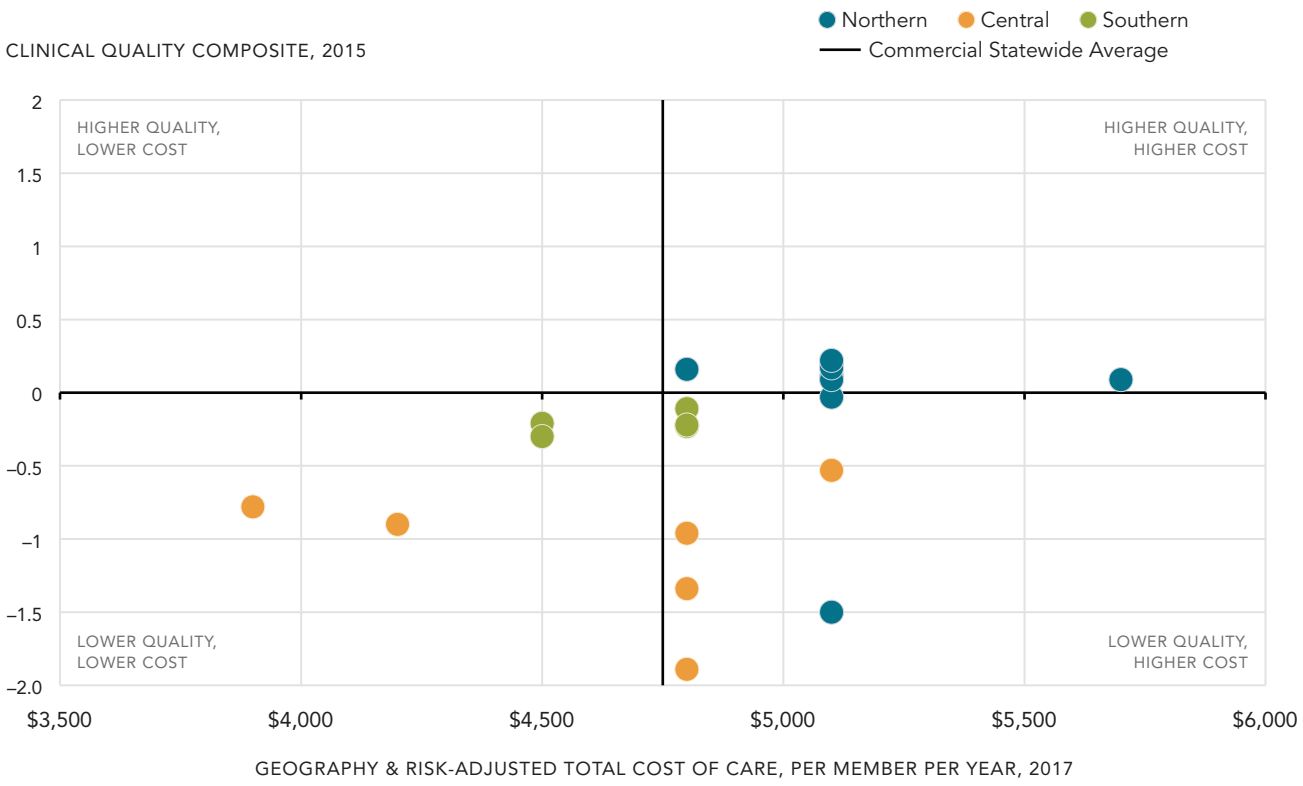
Figure 10 compares the clinical quality composite score (for the 10 clinical quality measures available for 2015) and the average total risk-adjusted cost of care for each region in California. Regions are grouped into three "super regions" of the state — Northern, Central, and Southern.

Northern California regions (in the upper-right quadrant) typically provide better clinical quality but have the highest costs. Exceptions are the northern rural counties (in the bottom-right quadrant), which have both poor quality and higher-than-average costs. Santa Clara County (the blue dot closest to the vertical axis) also stands out as having above average quality and relatively low costs. Southern California counties (in green) have relatively average costs and slightly below average quality, while Central California counties (in orange) tend to have worse quality scores than other regions, and wide variation in costs.

The analysis does not suggest the "right" spending level for any region. However, the Atlas shows the wide variation in risk-adjusted costs. Although imperfect risk adjustment could be the source of some of the variation, the differences in costs suggest that some residents could be receiving poor value for their health care investment.

If the quality of care from the top-performing region were provided to all Californians, "nearly 570,000 more people would have been screened for colorectal cancer and 166,000 more women would have been screened for breast cancer in 2015," according to the Atlas.[24]

Figure 10. Quality vs. Cost in Commercial Insurance, by Region, California



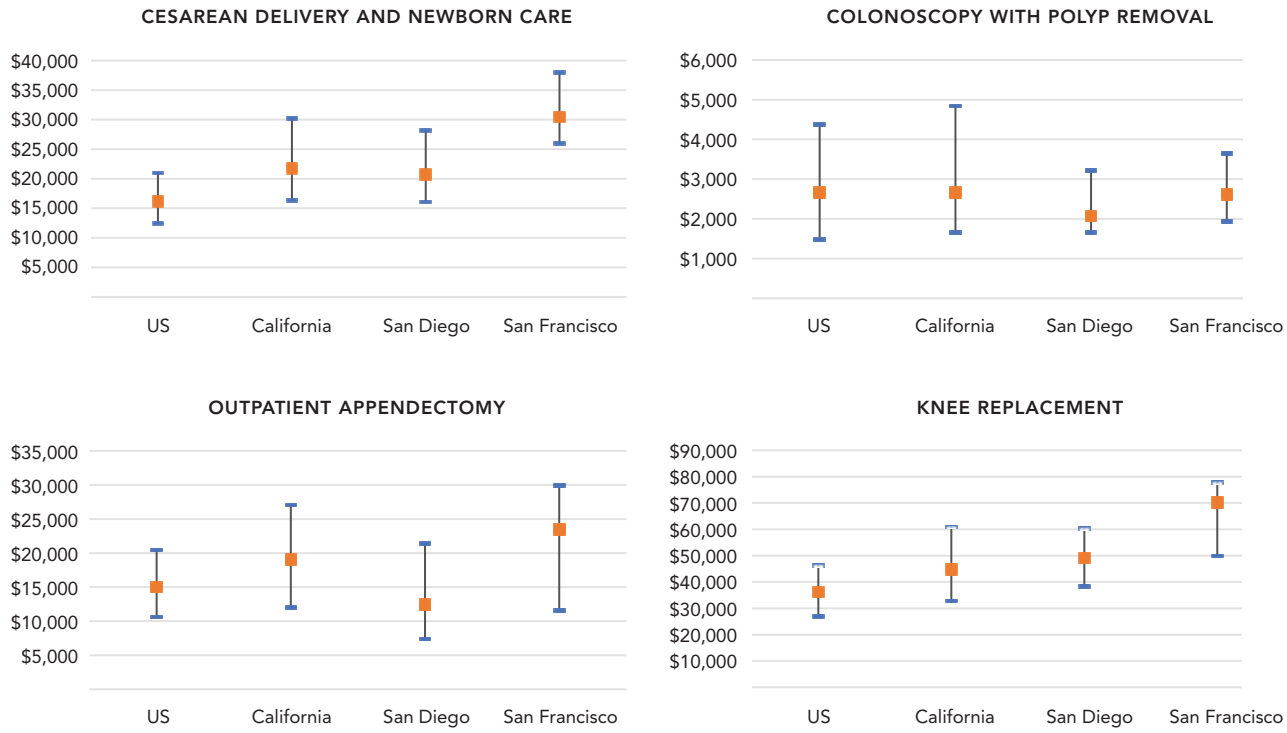
Source: Integrated Healthcare Association, California Regional Health Care Cost & Quality Atlas: Total Cost of Care - Geography and ACG Risk Adjusted - Commercial and Clinical Quality Composite - 2015 Measures - Commercial. 2017. Accessed January 10, 2020.

Price Disparities for the Same Procedures

The Atlas data above paint a disparate picture of health costs and quality statewide. The prices that private health plans pay for specific procedures also reveal wide disparities around the state. The Health Care Cost Institute (HCCI) has amassed more than 730 million claims from four insurers[25] and uses the data to assess variations in prices across the US. HCCI data for four common health care service bundles were assessed using the Guroo online price transparency tool, as seen in Figure 11.[26]

The substantial variation in prices for the same procedure shown in Figure 11 suggests that some consumers may be getting poor value for their dollars. For example, the average price of a cesarean delivery in San Diego was just over $20,000, compared with an average price of just over $30,000 in San Francisco. Even within a region, prices often vary substantially. For example, the minimum price for an outpatient appendectomy in San Diego is less than half the amount of the maximum price, according to the data. In general, average prices in California for these services are higher than average prices nationwide, although the wide range in prices indicates a high degree of overlap.

Figure 11. Price Ranges for Four Common Health Care Services, US, California, San Diego, and San Francisco



Note: Data are based on claims paid between July 1, 2014, and June 30, 2016, trended forward to 2018 price levels.

Source: Authors' calculations based on Guroo Price Transparency Tool. Accessed December 2019.

IV. Six Contributors to Wasteful Spending

The large price disparities among regions in California described above suggest substantial waste or inefficiency in the system. If health care policymakers addressed waste and inefficiency, they could significantly lower the cost of care.

In their 2019 update of a landmark report by the IOM, Shrank et al. estimated that between one-fifth and one-quarter of the nation's health care spending was the result of wasteful and unnecessary spending, as well as missed opportunities to provide appropriate care.[27] Assuming that the proportion of wasteful and unnecessary spending is similar in California, the state could save between $58 and $73 billion per year by eliminating waste and improving efficiency.

This section explores six contributors to wasteful spending and examines their relevance to costs in California. Options for reducing health spending in a number of these areas are covered in the second report in this series.

Overtreatment

Nationwide, overtreatment accounts for up to $76 to $101 billion in health spending annually.[28] Factors that contribute to overtreatment include ordering duplicate tests, prescribing treatments that have little or no value, and ordering a high-cost treatment when a lower-cost treatment could have resulted in equivalent or superior quality of care. Some patients and doctors believe that more treatment is better. The availability (or supply) of health care treatments may also cause patients and doctors to use them more, regardless of their clinical benefit.[29,30] Further, excessive prices and overtreatment may be related: If providing services of little or no clinical value is profitable, some providers may continue to offer them despite the limited benefit.

The Choosing Wisely initiative, which the ABIM (American Board of Internal Medicine) Foundation launched in 2012 in partnership with *Consumer Reports*, seeks to identify commonly used tests and procedures that may be unnecessary. The initiative provides information about these services to help patients and providers make better decisions.[31,32] Based on recommendations from Choosing Wisely, stakeholders in California recently formed Smart Care California, a consortium of payers that includes CalPERS (the California Public Employees' Retirement System), Medi-Cal, and Covered California. The group promotes best practices for reducing overtreatment in three areas: inappropriate opioid prescribing, unnecessary cesarean sections, and unnecessary imaging for low back pain. According to Smart Care California data, the state saw sizable reductions in inappropriate opioid prescribing and small reductions in cesareans for low-risk, first-time mothers from 2015 through 2017.[33]

While the Smart Care initiative is a step toward reducing unnecessary care, additional opportunities to expand and build on this capacity exist. California's all-payer claims database (APCD), which is in development, may enable policymakers to identify patterns about low-value care and, ultimately, take action to address waste. For example, the Minnesota Department of Public Health used its APCD to show $55 million in spending on 18 low-value services in 2014. The most common low-value service was diagnostic imaging for uncomplicated headaches.[34] A similar study used Virginia's APCD to estimate that more than $586 million in spending went to 44 low-value services, including baseline lab tests for patients having low-risk surgery, annual cardiac screening for asymptomatic patients, and routine imaging for uncomplicated rhinosinusitis.[35]

Failures of Care Delivery and Inadequate Prevention

Shrank et al. estimated that the US spends $102 to $166 billion each year, or 14% to 18% of all avoidable health spending, treating conditions that are preventable, unnecessary, or avoidable.[36] These missed opportunities include primary prevention (avoiding an illness or injury), secondary prevention (screening to identify health issues at an early stage), tertiary prevention (managing diseases post-diagnosis), avoidable

conditions such as hospital-acquired infections, and excess costs stemming from clinical inefficiency.

While reducing hospital-acquired infections and clinical inefficiencies will both improve health care quality and reduce costs, prevention is something of a mixed bag in terms of cost containment. Prevention can save money in many important ways, such as by reducing the cost of treating diseases by detecting them earlier and avoiding treatment altogether. But in other ways, prevention can increase costs when poorly targeted.

While the IOM points to some specific opportunities to save money by expanding access to treatment, in general the literature shows that expanding access to preventive care increases spending.[37] Preventive services must typically be provided to a large share of the population, many of whom will not have the condition. Among those who screen positive, savings will only materialize if lower-cost treatments can stave off costlier treatments down the road. In a review of the literature, Cohen, Neumann, and Weinstein found that most preventive services both add value to the health system and increase total costs.[38] Similarly, a recent review of disease management programs found cost savings in only a minority of cases.[39]

Nevertheless, as both Shrank et al. and the IOM concluded, certain types of preventive services can save money, particularly if targeted to high-risk populations. For example, certain colorectal cancer screening approaches have been found to reduce total health spending for people in targeted age groups,[40] as have disease management programs for congestive heart failure.[41] In many cases, preventive services enable people to live longer, healthier lives, making the services a good investment even if they cause overall health care spending to increase.

According to the National Healthcare Quality and Disparities Reports, California scores average relative to other states in terms of providing preventive care, and weak relative to other states in terms of managing chronic conditions through preventive care.[42] Among the prevention measures considered, California scored poorly on influenza and pneumococcal vaccinations and cholesterol measurement. The state scores in the average range for many vaccines provided to children and adolescents, and for depression treatment among those who have experienced a major depressive episode. Areas of strength include preventive care measures related to colorectal and cervical cancer screening, and chronic care measures related to HIV management.

Failures of Care Coordination

Although some people disagree about the meaning of "care coordination," the Agency for Healthcare Research and Quality (AHRQ) defines it as a process in which a provider or other person in the health care system takes responsibility for managing a patient's course of care across multiple settings, including home, community, primary, inpatient, and other care.[43] Failures of care coordination occur when a patient's care is disjointed, such as when there is poor communication across multiple providers caring for a patient, potentially leading to lapses, oversights, or redundancies in treatment.[44] Individuals with complex chronic conditions, who use more services and may interact with many providers, are at particular risk for coordination failures. At a national level, failures of care coordination that may lead to avoidable or unnecessary medical complications and hospital admissions account for approximately $27 to $78 billion in excess spending. However, the California profile is a bit different, possibly due to the high adoption of managed care in the state, which may facilitate care coordination if patients are treated in an integrated delivery system with established protocols for sharing information. In the most recent version of the National Healthcare Quality and Disparities Report,[45] California's ratings in the priority area of care coordination were above average.[46]

Still, the state has room for improvement. For example, a recent assessment of the Cal MediConnect Program — which attempts to integrate and coordinate Medicare and Medi-Cal services for those eligible to participate in both programs — found that while enrollees said they were more satisfied with benefits and thought the quality of care was better because

of the program, there was no improvement in care coordination.[47]

Administrative Complexity

Shrank et al. estimate that high administrative expenses contribute to roughly $266 billion in overspending nationwide.[48] A comprehensive 2005 accounting of administrative costs for private insurers, physician groups, and hospitals in California found that commercial insurers in the state spend roughly 10% of revenue on administration, physician groups spend about 27% of revenue on administration, and hospitals spend about 21% of revenue on administration.[49] CALPIRG (the California Public Interest Research Group) estimated in 2008 that administrative activities consumed 5% of total health spending in California, although the data may be outdated.[50]

California has several unique features that may contribute to high administrative costs. First, a ban on the corporate practice of medicine, which aims to separate the "professional standards and obligations" of medical professionals and the "profit motive of the corporate employer," prohibits corporate entities from employing physicians or owning physician entities.[51] This may lead to inefficient behaviors, such as hospitals having to establish or contract with a medical foundation that can employ physicians.

In addition, California remains the only state in which two agencies regulate health insurance, which adds an additional layer of administrative complexity. The Department of Managed Health Care oversees most health maintenance organizations (HMOs), covering about 21.6 million Californians. The California Department of Insurance regulates most preferred provider organizations (PPOs) and traditional fee-for-service plans, covering about 2.4 million people. The dual structure has been described as confusing and inefficient, with the potential for regulatory inconsistencies.[52] Potential options for regulatory reform include consolidating the two agencies and institutionalizing coordination and consistency between them.[53] However, at present, both agencies continue to operate independently.

Finally, California's 13 million Medi-Cal beneficiaries receive their health care through six models of managed care.[54] This relatively complex approach to administering the Medi-Cal program has the potential to increase administrative costs.

Pricing and Market Inefficiencies

As noted in the discussion of data from HCCI above, prices for health care services are often higher in Northern California compared with the statewide average. Increased market concentration plays an important role. In March 2018, California Attorney General Xavier Becerra brought a civil antitrust action against Sutter Health and its affiliates for using their market power in Northern California to increase prices, and therefore costs, for its health care services.[55] The suit alleged that Sutter prevented insurers from using "steering and tiering," which can be important tactics for gaining bargaining leverage against health care providers that dominate local markets. In late 2019, Sutter agreed to pay $575 million to settle the lawsuit, and also agreed to restrictions on out-of-network charges and practices viewed by the state as anticompetitive, such as requiring insurers to include all Sutter hospitals in their networks as opposed to individual hospitals ("all or nothing" agreements).[56] At the time of this writing, it is too early to know how the settlement will affect the market for health care in California.

Despite health care market consolidation, average health spending in California is lower than in the rest of the country by some measures. According to statistics compiled by the Kaiser Family Foundation using data from the Office of the Actuary of the Centers for Medicare & Medicaid Services, per-capita health spending in California — $7,549 — was lower than the national average of $8,045 in 2014 (the most recent year for which data are available).[57] Similarly, 2017 employer premiums in California were slightly below the national average, according to an analysis conducted by the Kaiser Family Foundation using data from the Medical Expenditure Panel Survey (MEPS) Insurance Component.[58,59]

One factor that may contribute to lower per-capita spending is the dominance of managed care in the state. HMOs cover 59% of eligible Californians, the highest rate of any state.[60] Kaiser Permanente accounts for a particularly large share of the California market. A recent assessment of accountable care organization (ACO) partnerships in California underscores Kaiser's strong competitive pressure in a community: "The more dominant Kaiser's presence, the stronger the incentive for other plans to develop new products at lower prices to maintain market shares."[61] In addition, the California population is relatively young compared with the national population,[62] and Medi-Cal payment rates for physician services are low relative to the national average,[63] although not for hospital care.[64]

Fraud and Abuse

Across the nation, Shrank et al. put the cost of health care fraud at between $59 and $84 billion.[65] The Federal Bureau of Investigation, the primary agency tasked with investigating fraud in the health care system, estimates that health care fraud costs US taxpayers $80 billion per year.[66] The most common types of fraud include billing for services that were never rendered — such as using genuine patient information, sometimes obtained through identity theft, to fabricate entire claims, as well as padding claims with charges for procedures or services that did not take place.

Major fraud investigations have produced multiple criminal filings, which provide some sense of the magnitude of the problem in California. For example, prosecutors in Los Angeles filed cases in 2018 alleging $660 million in fraudulent bills. The 33 defendants included doctors, pharmacists, and an attorney accused of kickback schemes involving surgeries, drugs, home health services, Medicare Part D prescriptions, and hospice care.[67] Also in 2018, the South San Francisco–based drug manufacturer Actelion paid $360 million to resolve claims that it illegally paid the copays of thousands of Medicare patients who used the drugmaker's hypertension drugs, including Tracleer, Ventavis, Veletri, and Opsumit.[68]

These recent actions in California indicate that fraud is an ongoing, and very likely a costly, concern in the state.

Extrapolating to California

The national estimates of wasteful spending are challenging to extrapolate to California given several factors raised above, including the higher prevalence of managed care in the state, the relatively younger population, and unique market consolidation patterns, particularly in Northern California. Nevertheless, if we use the Shrank et al. estimates[69] as a rough guidepost, we can infer that roughly $58 to $73 billion of total health spending in California is wasteful, with the largest shares of waste stemming from excessive administrative complexity (28% to 35%) and pricing and market inefficiencies (26% to 30%). Table 3 shows estimates of the breakdown of wasteful spending in California by category, assuming that the Shrank et al. national estimates can be applied at the state level.

Table 3. Estimated Breakdown of Wasteful Health Spending, by Category, California, 2014

WASTE CATEGORY	LOWER BOUND (%)	UPPER BOUND (%)	LOWER BOUND (BILLIONS)	UPPER BOUND (BILLIONS)
Administrative complexity	34.9%	28.4%	$20.3	$20.7
Pricing and market inefficiencies	30.4%	25.7%	$17.6	$18.8
Failures of care delivery and inadequate prevention	13.5%	17.7%	$7.8	$12.9
Overtreatment	10.0%	10.8%	$5.8	$7.9
Fraud and abuse	7.7%	9.0%	$4.5	$6.5
Failures of care coordination	3.6%	8.4%	$2.1	$6.1
Totals	**100%**	**100%**	**$58**	**$73**

Notes: The lower bound estimates assume it is possible to eliminate 20% of health spending ($58 billion), and the upper bound estimates assume it is possible to eliminate 25% of health spending ($73 billion). Totals may not sum due to rounding.

Source: Estimated percentages come from Shrank WH, Rogstad TL, Parekh N. "Waste in the US Health Care System: Estimated Costs and Potential for Savings." *JAMA*. Oct 7, 2019; 322(15):1501–1509.

V. Conclusion

One of the three primary goals of 2010's Affordable Care Act was to stimulate efforts nationwide to contain health care costs. However, health spending continues to outpace inflation and remains a major challenge nationally and within California.

The high cost of care is a significant source of stress for Californians, particularly for the poor and those with chronic conditions, who often have to choose between paying for food and utilities and paying for doctor visits and prescription drugs. Businesses of all sizes struggle to afford the rapidly rising costs of providing health care to their employees. And prices themselves remain stubbornly high in many regions due to market consolidation and other factors.

Although many stakeholders agree that controlling health care spending should be a priority, little consensus exists about how to achieve that goal. In the next report in this series, we will take a step toward addressing that issue as we explore the policies that have the strongest potential to move the needle on cost containment.

California has always been a national leader in the development of health policy and in creating and scaling up innovative approaches to reducing health care costs. Governor Gavin Newsom's recent creation of the Office of Health Care Affordability provides a fresh opportunity to redouble our collective efforts to tame the inexorable rise in health spending.

Appendix A. Methodology

Background on the MEPS

The Medical Expenditure Panel Survey Household Component (MEPS-HC) is an annual panel survey of households that began in 1996 and is conducted by the Agency for Healthcare Research and Quality (AHRQ). Data from MEPS are widely used to examine health care costs and utilization. MEPS combines detailed survey information with spending and utilization data that are validated through the patient's insurer and provider. To produce estimates for California, the team used restricted-access state identifiers made available for this project through AHRQ project number 466 and Census Bureau project number 2169. The research for this report was conducted at the AHRQ's Center for Financing, Access and Cost Trends (CFACT) Data Center, and the support of AHRQ is acknowledged. The results and conclusions in this paper are those of the authors and do not indicate concurrence by AHRQ or the US Department of Health and Human Services.

The research team used MEPS data from 2000 through 2016, the last year for which we had access to the data. (Data from the MEPS Insurance Component, an employer survey, are released on a different schedule.)

An advantage of the MEPS relative to other data sources such as State Health Expenditure Accounts (SHEA) data from the Office of the Actuary (OACT) of the Centers for Medicare & Medicaid Services (CMS) is that it is disaggregated, allowing the user to analyze specific categories of health spending. However, while MEPS is designed to be nationally representative, the estimates are not necessarily representative of the population of California.

MEPS reports aggregated annual data files and medical event files for specific sites of care (such as hospital inpatient care, hospital outpatient care, office visits, and prescription drugs). For this report, the team used data from both the full-year consolidated files and the medical event files.

Health Spending Estimates

The MEPS data result in smaller spending estimates than those found in the CMS SHEA data due in part to an undercount of high spenders. The MEPS estimates were adjusted to address this undercount using the method described by Bernard et al.[70] After adjustment, California health spending in the MEPS was $213 billion in 2016. Even with these adjustments, the MEPS figures are lower than those reported by the National Health Expenditure Accounts (NHEA), because MEPS excludes certain categories of health care, including long-term care, public health spending, health-related investments and philanthropy, and over-the-counter medications. The approach used to adjust the MEPS data is described in detail below.

Weighting

To account for MEPS undercounting,[71] prior research upweights MEPS spending categories to better align with the CMS National Health Expenditure Accounts (NHEA). Bernard et al.[72] propose using the weights shown in Table A1 for specific sources of payments.

Table A1. MEPS Weights to Align with NHEA Benchmarks

PAYMENT SOURCE	WEIGHTS TO ALIGN WITH NHEA BENCHMARKS
Out of pocket	9.47%
Private health insurance	30.51%
Medicare	14.28%
Medicaid/Children's Health Insurance Program (CHIP)	38.84%
Department of Veterans Affairs	–9.94%
Workers' compensation insurance	112.40%
Other federal	0.00%
Other state and local	0.00%
Other sources	0.00%
All expenditures	**23.10%**

Source: Bernard D, Selden TM, Pylypchuk YO. Aligning the Medical Expenditure Panel Survey to Aggregate U.S. Benchmarks, 2010 (PDF); Working Paper No. 15002. 2015. Accessed April 5, 2019.

Spending estimates for the present analysis were reweighted by increasing the raw numbers by the percentage factors shown in Table A1. As an example, a private health insurance expenditure of $100 in the 2016 MEPS would be increased by a factor of 30.51%, to $130.51. Unlike the other spending estimates, VA spending is reduced, because this category of expenditure is overestimated in the MEPS relative to the NHEA. California-specific MEPS-HC spending estimates shown in this document are reported in 2016 dollars, weighted for MEPS undercounting. Medical spending is also reported by insurance plan.

Insurance Hierarchy

Because some individuals in MEPS report having insurance from more than one source, the following hierarchy was used to classify individuals into mutually exclusive groups: Medicaid, Medicare, employer-sponsored insurance, other government insurance (including TRICARE and other public plans), non-group plans (including those purchased through Covered California), and the uninsured. Individuals with miscellaneous private insurance who are not classified as having Medicare, Medicaid, or employer-sponsored plans are included in the non-group category.

Trends

In order to understand trends in medical spending in California, the team used the MEPS full-year consolidated data files for 2000–2016. The team's trend analysis differs from the expenditure analysis described above in two key ways. First, medical spending for years prior to 2016 was inflated to 2016 dollars using the California Consumer Price Index (CPI) for urban consumers. Second, since the distribution of medical spending is highly influenced by a small number of high-cost patients, observations in the top 1% of the spending distribution were replaced with the 99th-percentile expenditure in each category. While very high-cost individuals are an important feature of overall health spending in California, in finite survey samples they distort underlying trends. For that reason, we recategorized spending for these individuals in the trend analysis, although all observations were kept when reporting total spending. This accounts for discrepancies between total spending estimates and the trend estimates.

Gross State Product (GSP) Calculations

The team calculated total per-capita health care expenditures in California as the sum of personal expenditures ($7,549 in 2014[73]) and nonpersonal expenditures ($1,474 in 2014[74]). Nonpersonal expenditures include government health care administration, net costs of private health insurance, government public health activities, and investments in research, structures, and equipment. California per-person nonpersonal expenditures are assumed to equal the national average. Health expenditures as a share of GSP are then ($7,549 + $1,474) / $61,957 = 14.6%, where the denominator is California's GSP per capita as estimated by the US Bureau of Economic Analysis.[75]

Endnotes

1. The statistics reported in this paragraph were compiled based on California-specific data for 2018 reported by the Agency for Healthcare Research and Quality as part of the Medical Expenditure Panel Survey Insurance Component State and Metro Area Tables.
2. Hamel L, Wu B, Brodie M, Aliferis L, Stremikis K, Antebi E. The Health Care Priorities and Experiences of California Residents. 2019. Accessed March 16, 2019.
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5. Shrank WH, Rogstad TL, Parekh N. "Waste in the US Health Care System: Estimated Costs and Potential for Savings." *JAMA*. Oct 7, 2019; 322(15):1501–1509.
6. Hamel L, Wu B, Brodie M, Aliferis L, Stremikis K, Antebi E. The Health Care Priorities and Experiences of California Residents. 2019. Accessed March 16, 2019.
7. Department of Finance. California State Budget — 2019–20: Summary Charts. 2019. Accessed January 9, 2020.
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9. Centers for Medicare & Medicaid Services. Health Expenditures by State of Residence, 1991–2014. 2017. Accessed April 5, 2019.
10. California accounted for 10.4% of total national health spending, although California accounted for 12.1% of the US population. In 2014, health expenditures were 14.6% of gross state product (GSP), compared with 17.3% of gross domestic product for the broader country. However, these differences are not direct comparisons, because California has a higher GSP than many other states. While the CMS data are the most comprehensive available estimates of total spending in the state, they are relatively outdated. See Appendix A for a discussion about the methodology.
11. To produce estimates for California, the team used restricted-access state identifiers made available for this project through AHRQ project number 466 and Census Bureau project number 2169. The research for this report was conducted at the AHRQ's Center for Financing, Access and Cost Trends (CFACT) Data Center, and the support of AHRQ is acknowledged. The results and conclusions reported here are those of the authors and do not indicate concurrence by AHRQ or the US Department of Health and Human Services.
12. To show trends, historical spending numbers have been adjusted to 2016 dollars using the California Consumer Price Index (CPI) for urban consumers. This adjustment eliminates changes in spending due to general inflation while preserving portions of the trends that are due to changes in utilization and increases in relative price levels.
13. Medi-Cal is California's Medicaid program.
14. Federal expenditures on Medi-Cal are determined by Medicaid's Federal Medical Assistance Percentage (FMAP). California receives the minimum FMAP payment, 50%, for those who were eligible for Medi-Cal prior to the enactment of the Affordable Care Act (ACA). However, the ACA increased federal payment for Medi-Cal enrollees who were made newly eligible for coverage under the law.
15. McConville S, Warren P, Danielson C. Funding the Medi-Cal Program. 2017. Accessed April 5, 2019.
16. To construct the trend charts, outliers were removed by replacing the top percentile of spending in each year and by each source of spending with the 99th-percentile expenditure in that category. This accounts for minor differences between estimates in Table 1 and the figures.
17. The MEPS-IC is a survey of employees fielded by AHRQ that collects information about health insurance premiums, employee contributions, and the type of health insurance employers offer. Because access to the restricted-use MEPS-IC was not available for this project, the analysis relied on aggregate tables reported on AHRQ's website.
18. Agency for Healthcare Research and Quality. Private-Sector Data by Firm Size and State, Table II.B.2.b.(1) Percent of Private-Sector Enrollees That Are Enrolled in Self-Insured Plans at Establishments That Offer Health Insurance by Firm Size and State: United States, 2017. 2017. Accessed April 5, 2019.
19. Historically, the MEPS-IC data only reported deductible data based on firms within two size categories (those with fewer than or greater than 50 workers). In addition, the MEPS-IC data do not contain deductible information for the year 2000.
20. Integrated Healthcare Association. California Regional Health Care Cost & Quality Atlas, Fact Sheet. 2018. Accessed March 16, 2019.
21. Integrated Healthcare Association. California Regional Health Care Cost & Quality Atlas, Fact Sheet. 2018. Accessed March 16, 2019.
22. The California Regional Health Care Cost & Quality Atlas is a collaboration of the Integrated Healthcare Association, the California Health Care Foundation, and the California Health and Human Services Agency. The third edition of the Atlas, published in 2018, integrates multi-payer data from three years (2013, 2015, and 2017), covering HMO and PPO products, Medicare Advantage, Medicare fee-for-service, Medi-Cal managed care, and Medi-Cal fee-for-service.
23. Yanagihara D, Kline A, Yegian J. Benchmarking California Health Care Quality and Cost Performance; Issue Brief No. 21. 2016. Accessed March 16, 2019.

24. Integrated Healthcare Association. California Regional Health Care Cost & Quality Atlas, Fact Sheet. 2018. Accessed March 16, 2019.

25. The four insurers are Aetna, Humana, Kaiser Permanente, and UnitedHealthcare.

26. The HCCI/Guroo data represent claims incurred between July 1, 2014, and June 30, 2016, and have been projected to reflect prices for 2018.

27. Shrank WH, Rogstad TL, Parekh N. "Waste in the US Health Care System: Estimated Costs and Potential for Savings." *JAMA*. Oct 7, 2019; 322(15):1501–1509.

28. Shrank WH, Rogstad TL, Parekh N. "Waste in the US Health Care System: Estimated Costs and Potential for Savings." *JAMA*. Oct 7, 2019; 322(15):1501–1509.

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35. Mafi JN, Russell K, Bortz BA, Dachary M, Hazel WA, Jr., Fendrick AM. "Low-Cost, High-Volume Health Services Contribute the Most to Unnecessary Health Spending." *Health Aff (Millwood)*. Oct 1, 2017; 36(10):1701–1704.

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CHCF

Commissioning Change:
How Four States Use Advisory Boards to Contain Health Spending

JANUARY 2020

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About the Foundation

The California Health Care Foundation is dedicated to advancing meaningful, measurable improvements in the way the health care delivery system provides care to the people of California, particularly those with low incomes and those whose needs are not well served by the status quo. We work to ensure that people have access to the care they need, when they need it, at a price they can afford.

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Introduction

Controlling the growth of health care spending is central to any state effort to achieve universal coverage and to bring relief to consumers struggling with premiums and out-of-pocket costs. As it pursues these goals, California can learn from several states that have established state commissions to measure, monitor, and set targets to control health care cost increases.

Four states — Maryland, Massachusetts, Oregon, and Rhode Island — have well-developed regulatory bodies or independent authorities aimed at controlling growth in health spending in their states. No single blueprint exists for these state health care spending commissions. Each state has taken its own path. (Detailed descriptions of each state commission are included in Appendix B.) However, a closer look at these models offers valuable lessons for California and other states looking to emulate their successes and plan for the inevitable trade-offs.

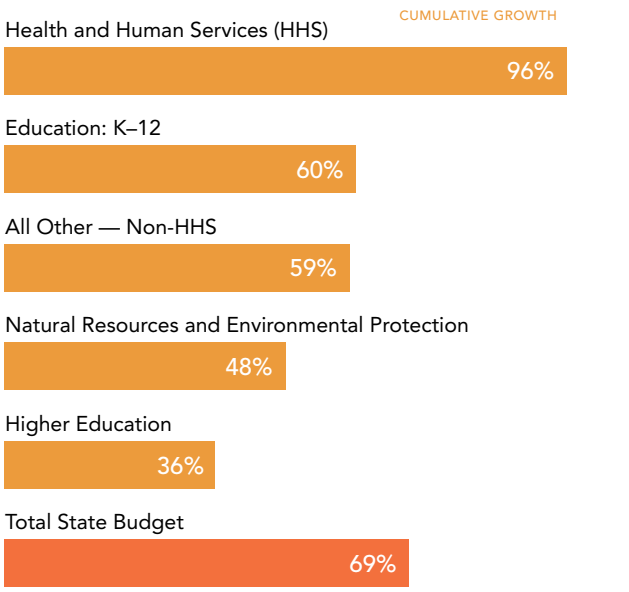
California can learn from several states that have established state commissions to measure, monitor, and set targets to control health care cost increases.

Health Spending at the State Level and Why It Matters

Rapidly growing health care expenditures have long challenged state policymakers. Over the last 10 years, California state budget expenditures on health and human services grew by 96% from 2009 through 2018, while spending on all other non-HHS programs increased by 59% (see Exhibit 1). Similarly, state spending on health care programs in Massachusetts grew 57% between 2009 and 2018, more than double the percentage increase on education, public safety, and the environment (Exhibit 2, page 4).

States are not always getting good value for their dollars spent: This unprecedented spending has not resulted in a commensurate rise in quality of care. Among US states, risk- and wage-adjusted spending per enrollee across Medicare and Medicaid shows no consistent relationship with quality.[1] Even within

Exhibit 1. California State Spending, by Category
FY 2009–10 to FY 2018–19



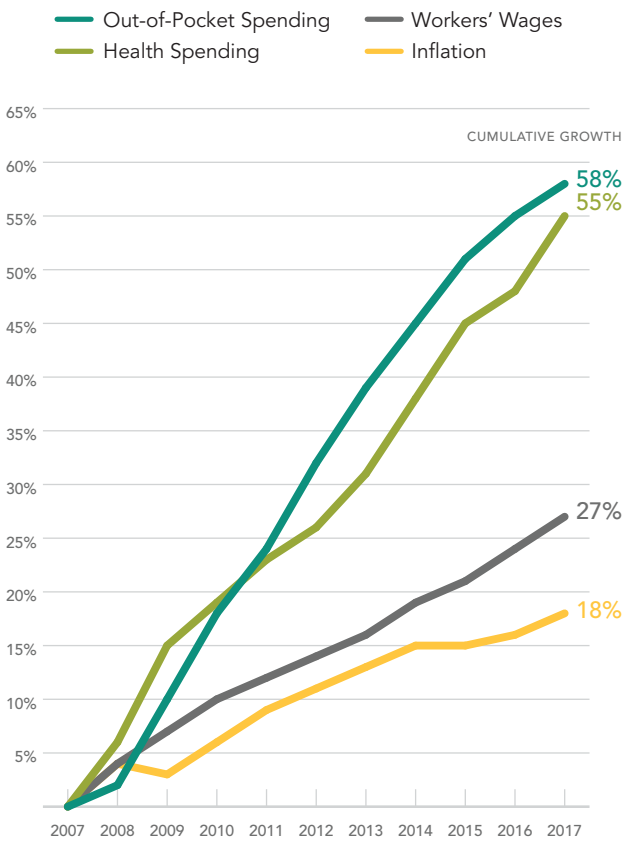
Sources: *Enacted Budget Summary – All Chapters* (2009–10), State of California, n.d.; and *Enacted Budget Summary – All Chapters* (2018–19), State of California, n.d.

Exhibit 2. Massachusetts State Spending, by Category
FY 2009–10 to FY 2018–19

*Includes debt service, pension, and administration.

Source: "Massachusetts State Budget," Massachusetts Budget and Policy Center, n.d.

Exhibit 3. US Health Spending Is Growing Faster Than Wages and Inflation, 2007 to 2017



Source: Matthew Rae, Rebecca Copeland, and Cynthia Cox, "Tracking the Rise in Premium Contributions and Cost-Sharing for Families with Large Employer Coverage," Peterson-KFF, August 14, 2019.

states, including California, health spending can vary substantially across geographic regions with no observable differences in health outcomes.[2]

The high and rising cost of health care is also hitting family budgets hard. Many families are struggling to pay for double-digit premium increases and rising out-of-pocket expenses in an environment of slow wage growth. For example, from 2007 through 2017, total out-of-pocket health spending by US households (including family contributions to health insurance premiums, co-insurance, and deductibles) grew a cumulative 58% while workers' average wages grew only 27% (see Exhibit 3).

California families are especially impacted. From 2003 through 2018, total health care–related spending for a family with employer-sponsored insurance cumulatively increased by 142%, while median household income in California grew 43% (Exhibit 4, page 5). As a result, average total health-related spending for a family with employer-sponsored insurance ($24,104) now represents more than one-third (34%) of median household income in California ($70,489). Increasingly, a growing share of the modest increases in household incomes is being used to pay for rising health care costs.

Exhibit 4. Rising Out-of-Pocket Costs Put Pressure on Household Budgets in California

	2003	2018	CUMULATIVE GROWTH
Employer Premium Contribution	$6,052	$15,730	160%
Family Premium Contribution	$2,452	$5,101	108%
Family Out-of-Pocket Health Spending	$1,465	$3,273	124%
Total Family Out-of-Pocket Health Spending	$3,917	$8,374	114%
Total Health-Related Spending (employer and family)	$9,969	$24,104	142%
Median Income in California	$49,300	$70,489	43%
Percentage of California Median Income:			
➤ Total Out-of-Pocket Health Spending (family)	8%	12%	
➤ Total Health-Related Spending (employer and family)	20%	34%	

Source: Matthew Rae, Rebecca Copeland, and Cynthia Cox, "Tracking the Rise in Premium Contributions and Cost-Sharing for Families with Large Employer Coverage," Peterson-KFF, August 14, 2019.

State polls reveal both the necessity and urgency of policy efforts to reduce health care spending. A recent *Los Angeles Times* survey found that 40% of adults with employer-sponsored coverage had problems paying medical bills during the last year, including bills for their portion of health insurance premiums, deductibles, copays, or unexpected expenses for themselves or a family member.[3] A Latino Community Foundation survey found that making health care more affordable was the number one policy priority for California's Latinos.[4] A 2019 survey of state residents by KFF (Kaiser Family Foundation) and the California Health Care Foundation revealed that more than 8 out of 10 state residents want the governor and legislature to prioritize making health care more affordable.[5]

The four states with health care cost commissions studied in this report share both similarities and differences with California. Given its geographic size and population, California's health care infrastructure is bigger and total health spending is much higher than the four states studied (Exhibit 5, page 6). When adjusted for population size, however, California is more comparable to these states. Health care spending has been rising as a percentage of family incomes, state budgets, and state economic growth in all the states studied. Forty-seven percent of Californians are now enrolled in HMOs — a substantial proportion, but also only 7 and 8 percentage points higher than Rhode Island and Massachusetts, respectively. Spending per state resident is lowest in California among the states studied, due in part to relatively low rates of Medicaid spending per enrollee.

Exhibit 5. State Summary Statistics

	CALIFORNIA	MASSACHUSETTS	MARYLAND	OREGON	RHODE ISLAND
Sociodemographics					
State Population	39,560,120	6,902,100	6,043,900	4,191,000	1,057,900
Percentage in Poverty (0%–199% of FPL)	27%	20%	19%	27%	24%
Percentage Uninsured	7%	3%	6%	7%	5%
Median Annual Income	$71,805	$77,385	$80,776	$60,212	$63,870
Health System Characteristics					
Hospitals — General Acute Care	341	64	49	60	11
Physicians — Active	112,906	36,506	24,676	12,149	4,988
HMO Enrollment — Total (millions)	18,128	2,617	1,983	1,330	0.418
HMO Enrollment — Percentage	47%	39%	33%	33%	40%
Health Care Spending (billions)	**$292**	**$71**	**$51**	**$32**	**$10**
Private Health Insurance Spending	$104	$24	$17	$10	$3
Medicare Spending	$65	$14	$11	$7	$2
Medicaid Spending	$84	$18	$12	$9	$3
As a Percentage of Gross State Product (GSP)	10.4%	13.1%	12.8%	14.1%	17.0%
Per Capita Health Spending					
Total Health Care Spending	$7,381	$10,326	$8,493	$7,616	$9,520
Per Capita Private Health Insurance Spending	$4,735	$5,302	$4,343	$4,232	$4,620
Medicare Spending per Enrollee	$11,833	$11,899	$12,000	$8,942	$10,901
Medicaid Spending per Enrollee	$4,193	$7,458	$7,324	$6,207	$7,983
Commercial Health Insurance Premium (per employee enrolled in a family plan)	**$19,567**	**$21,801**	**$19,237**	**$18,977**	**$18,623**
Employee's Share	$5,376	$5,693	$6,177	$5,913	$5,493
Employer's Share	$14,191	$16,108	$13,060	$13,064	$13,130
State Financial Statistics					
Total GSP (trillions)	$2,798	$543	$400	$227	$59
Total State Expenditures per Capita	$6,607.00	$8,097.00	$7,158.00	$9,665.00	$8,352.00
State Pension Liability — Percentage Funded	70%	60%	69%	83%	54%

Notes: *FPL* is federal poverty level. US federal poverty guidelines are published annually by the Office of the Assistant Secretary for Planning and Evaluation of the US Department of Health and Human Services. Data are most current available, please see source for dates associated with each data point.

Sources: "State Health Facts," KFF, n.d.; and HMO/PPO Rx Digest, 2016, Sanofi, 2016.

State Commissions a Tool to Address Rising Costs

The idea of using independent state commissions to control health spending is not new (Exhibit 6). Started in 1972, the Maryland Health Services Cost Review Commission (HSCRC) is the oldest commission of its kind in the country. HSCRC initially focused on setting payment rates for hospital services, although its scope has since expanded to include total hospital budgets and targets for total statewide spending per capita.

Rhode Island's Office of the Insurance Commissioner began conducting health insurance rate reviews in 2004, and it has recently added a Health Care Cost Trends Steering Committee tasked with setting a comprehensive statewide spending target.

Since 2009, the Oregon Health Authority (OHA) has focused on controlling costs for the state's Medicaid program and premium costs for state employee health plans. A formal committee charged with establishing a statewide growth benchmark for health care costs was created within OHA in 2019.

The Massachusetts Health Policy Commission (HPC) was established in 2012 to set a total statewide growth target for health care costs and to monitor how much individual systems and groups contribute in relation to overall spending trends.

Exhibit 6. Legislative History and Commission Structure

	MARYLAND	OREGON	MASSACHUSETTS	RHODE ISLAND
Year Formed	1972	2009	2012	2004
Most Recent Update	2018	2019	2017	2019
Commission/ Implementing Agency	Maryland Health Services Cost Review Commission (HSCRC)	Oregon Health Policy Board (OHPB)	Massachusetts Health Policy Commission (HPC)	Office of the Health Insurance Commissioner (OHIC)
Health Care Expenditure Target Role	Oversees hospital global budget system	Oversees design and implementation of Sustainable Health Care Cost Growth Benchmark program	Oversees statewide cost growth targets	Oversees annual premium growth targets
Commissioners	Appointed by governor	Nominated by governor, approved by senate	Appointed by governor, attorney general, and state auditor	Appointed by governor
Number of Commissioner Members	7	9	11	1 (the State Health Insurance Commissioner)
Commissioner Member Representation	Independent experts, payers, providers, and consumers	Independent experts, providers, labor, and consumers	Experts, consumers and labor; no industry health care stakeholders	State official

Source: Author review of state websites and interviews.

Varying Goals Among Cost Commissions

While varying in their structure, regulatory authority, and scope, all four state's health care cost-containment commissions establish targets to help make health care more affordable for individual consumers and to improve the value delivered by a wide range of health care entities. Each of these states has supplemented its growth targets for health care costs and premiums with information about health care quality, and several states explicitly promote reforms to payment and delivery systems that improve population health.

Each of the four states sets and measures its spending benchmarks differently. Maryland began regulating inpatient hospital payment rates for all payers. It has since expanded its scope and rate-setting model to set total hospital budgets for all inpatient and outpatient services among all payers. For example, each year, the HSCRC explicitly sets total revenue targets for each facility and determines the specific payment rates necessary to meet those targets. The broader focus on global budgets allows the commission to control total expenditures within the hospital sector, taking into account both prices and utilization. The state is exploring how to add physician services to its total cost framework.

Massachusetts measures total statewide health care expenditures for insured services, and it collects detailed data from providers and commercial health insurers and public payers in the state. In 2018, the state's target growth rate for health care costs was 3.1% — slightly below the growth rate of the overall state economy. The statewide health spending target is applied to a broad range of "health care entities," which include health insurance payers, hospitals, clinics, and medical groups. Entities that grow faster than the target growth rate are subject to detailed reviews and may be required to submit improvement plans designed to bring their spending growth in line with the target.

Oregon's model focuses on setting targets for total Medicaid spending and limiting the growth of public employee health plan costs. In 2019, the target growth rate for costs was 3.4% for both Medicaid and public employee health plans. The state applies overall targets to individual organizations, including participating coordinated care organizations (CCOs). To enforce its targets, health plans covering public employees can impose price caps on hospital services (200% of Medicare payment rates) as part of contract negotiations.

Rhode Island is the only one of the four states studied that focuses its target growth benchmark on commercial insurance premiums. In 2019, the state's target rate of premium growth was 3.2%, a level tied to the projected growth of the state's Gross State Product. This target is applied to health insurance products sold in the fully insured commercial market. The Office of Health Insurance reviews proposed insurance products and premium rates for the coming year. The state commissioner can require changes, including reductions in rates as well as requirements for specific plan benefits that must be included (such as smoking cessation) before the commissioner approves plans for the coming year.

Finally, as mentioned above, all four states have explicit goals for transforming the delivery system and improving quality. Oregon has adopted a wide range of additional performance measures related to health care access, quality, experience of care, and health status for populations covered by CCOs, using data from the National Committee for Quality Assurance (NCQA) and the Agency for Healthcare Research and Quality. To foster coordinated care, the Massachusetts Health Policy Commission develops standards for the formal certification of patient-centered medical homes within its Medicaid program, as well as the certification of accountable care organizations (ACOs). Maryland has set specific quality targets to lower rates of hospital readmission and hospital-acquired infection below the national average. To foster more coordinated care, Rhode Island has set a target of 80% of primary care physicians practicing in patient-centered medical

homes, and the state has also adopted selected targets for improving quality and outcomes from NCQA and the Healthcare Effectiveness Data and Information Set.

Cost Commissions and Data

Targeting and monitoring performance in relation to benchmarks requires a sophisticated data infrastructure and analytic capability in each state (Exhibit 7). Measuring total cost or quality is generally calculated on an annual basis and is based on highly aggregated reports that summarize large data sets. Analyzing, monitoring, and enforcing targets at the level of an individual plan, facility, or medical group requires much more disaggregated data and more sophisticated analyses of patient-level risk adjustments and other factors affecting spending and outcomes.

All-payer claims databases (APCDs) represent the single most important data source among all four states in the study. Some states collect data and build their APCDs directly via a state agency — in Massachusetts, the Center for Health Information and Analysis (CHIA) is responsible for data collection, analysis, and reporting, for example. All state commissions have access to member-level Medicaid claims data, given the substantial proportion of Medicaid enrollees in each state and federal policy goals for improving value across the entire health care market. California is currently building an APCD through the Office of Statewide Health Planning and Development.[6] That effort is expected to include Medicaid data and to be substantially implemented by 2023.[7]

Measurement and analysis of total cost growth rates requires data at the level of patients, claims, and populations. All states in the study have either developed the capacity to link disparate data sources or have requested specific data sets that match service costs to patient and provider identifiers. While this places an additional reporting burden on organizations submitting patient-level data, federal health care privacy laws such as the Health Insurance Portability and Accountability Act allow "protected" data to be submitted to "health oversight agencies," including the state-level commissions included in this study.

Exhibit 7. Data Collection and Support for State Cost Commissions

	MARYLAND	OREGON	MASSACHUSETTS	RHODE ISLAND
External/Supplemental Data Collection and Support	Yes	Yes	Yes	Yes
Data Collection and Support Agency	Chesapeake Regional Information System	Oregon Health Authority, Oregon Insurance Division	Massachusetts Center for Health Information and Analysis	Executive Office of Health and Human Services

Source: Author review of state websites and interviews.

Strengths and Limitations of Current Models

Each of the four state cost-containment commissions included in this study offers important insights for those considering implementing reforms in other states. First, Maryland's HSCRC sets fixed growth targets and has the regulatory authority to enforce stringent compliance with targets (Exhibit 8). This has improved the ability of hospitals to manage costs and has produced savings from the program. While the program is limited to hospital spending, this segment remains the largest component (about one-third) of total health spending, as well as the main driver of overall cost increases in recent years. At the same time, the Maryland model does not easily allow for the transition to value-based models such as ACOs, which provide incentives to improve health status, health care quality and utilization, and population health. Finally, Maryland's model is built on a broad Medicare waiver that many observers consider unlikely to be offered to other states.

The Massachusetts Annual Growth Target and Statewide Benchmark model offers the most comprehensive framework for measuring total health care expenditures and for setting statewide targets that cover total health expenditures for the entire population (Exhibit 9, page 11). One advantage of the Massachusetts program has been broad support from stakeholders. For example, insurers voluntarily submit claims and other data for the self-insured commercial population. Under federal law, states cannot compel plans to supply self-insured data. One potential limitation of the Massachusetts model is the lack of a formal enforcement mechanism. While the HPC may require entities that exceed the growth target to submit justifications and performance improvements plans, the commission has no formal authority to sanction individual plans, hospitals, and medical groups that may be unduly contributing to state health spending increases.

Under Rhode Island's Health Insurance Premium Review Model (Exhibit 10, page 11), the state has authority to regulate premiums for the fully insured

Exhibit 8. Maryland Model: All-Payer Global Revenue Budgets for Hospitals

STATE-LEVEL PROGRAM ATTRIBUTES	STRENGTHS	LIMITATIONS	FUTURE CHALLENGES	BUILDING BLOCKS IN CALIFORNIA
Sets Global Revenue Budgets for All Hospitals	Effectively controls spending for the largest component of health care costs for all payers Sets statewide target for total spending for all payers	Limited to hospitals only Patient population and attribution difficult under hospital global budgeting	Complexity establishing and maintaining global budgets, avoiding regulatory capture Measure spending across hospital types (DRG, Type A, B, & C hospitals), services, and adjusting for patient mix	OSHPD currently collects detailed and comprehensive hospital data and patient-level data
Transitions Rural Hospitals from Cost-Based Reimbursement to Global Budgets	Provides predictable, stable revenue and cash flows for rural hospitals	Accounting for factors outside hospital control; preventing or adjusting for "leakage" of care from hospital to nonhospital (uncapped) setting	Adequate operational infrastructure	
Provides Financial Incentivizes for Prevention and Population Health	All providers working toward incentives for efficiencies Coordinate solutions to primary care issues	Potential difficulty obtaining federal approval through waivers	Long-term federal waiver authority not guaranteed Integration of quality measures	

Source: Author review of state websites and interviews.

Exhibit 9. Massachusetts Model: Total Health Care Spending Growth Target and Transparency and Reporting

STATE-LEVEL PROGRAM ATTRIBUTES	STRENGTHS	LIMITATIONS	FUTURE CHALLENGES	BUILDING BLOCKS IN CALIFORNIA
Establishes Single Target Growth Rate for All Payers and Providers	Explicitly links spending to affordability and economic growth	Potentially locks in existing high prices and other market-distorting factors	Updating statewide growth targets to incorporate other factors	California experience with cost of care analyses: IHA, Truven, others
Fixed, Stable, and Predictable Rate of Spending	Offers a single, transparent performance measure	Enforceability limited	Expansion of enforcement mechanisms if needed to address outliers	OSHPD currently collects detailed and comprehensive hospital data and patient-level data
Allows Market Flexibility to Meet Benchmark(s)	Demonstrated effectiveness based on Massachusetts experience	Does not explicitly address health disparities	Maintaining all-payer database to continue oversight of self-funded plans	OSHPD authorized to develop and administer new statewide health care all-payer claims database
Identifies Outliers and Requires Improvement Plans and Penalties	Recognizes and incorporates multiple factors that affect total cost growth including drug spending	Limited ability to control underlying drug costs	Integration of quality measures	
Provides Funds for Distressed Hospitals	May offer method for stabilizing rural hospitals	Does not explicitly address long-term economic trends	Development of long-term sustainable model	
Provides Funds for Infrastructure Development	Develops needed tools, data, and reporting regardless of provider type or payer source			

Exhibit 10. Rhode Island Model: Health Insurance Premium Regulation

STATE-LEVEL PROGRAM ATTRIBUTES	STRENGTHS	LIMITATIONS	FUTURE CHALLENGES	BUILDING BLOCKS IN CALIFORNIA
Review and approve health insurance premium rates — fully insured, commercial plans only	Directly regulates growth of one component of total health cost growth	Does not directly address provider market structure and performance factors that may affect premium growth; covers only fully insured population	Updating premium growth targets and impacting other factors including provider costs	California experience with health insurance reporting and rate review: Department of Insurance (DOI) and Department of Managed Health Care (DMHC)
Establish a global health spending cap for Rhode Island tied to economic growth	Explicitly links spending to affordability	Data needed for monitoring and enforceability are limited	Expansion of data reporting systems and enforcement mechanisms	California experience with cost of care analyses: IHA, Truven, others
Tie 80% of health care payments to quality	Recognizes the need to provide incentives for quality improvement	Data on quality are limited	Improvement in methods to measure quality to improve value	California experience with quality analyses: IHA, Medicare Compare, others
Develop a next-generation health information technology system for providers	Recognizes the need to improve data systems for comprehensive reporting and monitoring	Standardized IT and data systems not readily available	Development of comprehensive IT and data reporting systems that will provide comprehensive data	OSHPD currently collects detailed and comprehensive hospital data and patient-level data; DMHC and DOI collect health plan data

Source (Exhibits 9 and 10): Author review of state websites and interviews.

commercial population. The program has produced an estimated savings of $258 million from 2012 through 2018 and a projected savings of $22 million for 2019. These results demonstrate the effectiveness of a regulatory model that explicitly targets lower growth in health insurance premiums. Furthermore, the annual growth benchmark is tied to the underlying performance of the state's economy. However, while the program has produced savings to date, it does not currently have mechanisms in place to directly address underlying medical care costs within the state, such as health care utilization and provider prices. The lack of focus on medical costs, which make up 80% to 85% of premiums, may hamper efforts to moderate premium growth over the long term.

In Oregon, the OHA's focus has allowed the program to more directly control specific cost drivers within the Medicaid program and to limit hospital prices in commercial health plan contracts covering public employees (Exhibit 11). Although focusing on specific cost drivers can reduce spending, it can also create incentives for increases in utilization and shifts in care settings that ultimately do little to promote value. More recently, Oregon has endorsed the development of a health spending target for the entire population by 2020.

Considerations for California and Other States

Those considering and designing a cost-containment commission in California and other states can learn from these efforts:

1. Be Explicit About the Goals of the Cost-containment Commission.

Each of the states reviewed here has a different set of goals for its program, due in part to each state starting in a different period and evolving based on its own legislative history. Ultimately, each state wants to improve value in its health care system by limiting the growth of overall health care spending, in part to

Exhibit 11. Oregon Model: Regulation of Health Insurance Premium and Medicaid Program Costs

STATE-LEVEL PROGRAM ATTRIBUTES	STRENGTHS	LIMITATIONS	FUTURE CHALLENGES	BUILDING BLOCKS IN CALIFORNIA
Review and Approve Health Insurance Premium Rates for Public Employees	Directly regulates health cost growth for large commercially insured population	Does not directly address provider market factors that may affect premium growth; covers only one segment of fully insured population	Meeting premium growth targets and influencing underlying cost drivers including provider prices	California experience with health insurance reporting and rate review: Department of Insurance and Department of Managed Health Care
Control Total Cost Growth for Medicaid Program	Directly regulates health cost growth for government-funded, insured population	Does not directly address provider market factors that may affect provider costs; covers only portion of insured population	Meeting Medicaid program growth targets over the long run	California experience with selective contracting and managed care under the Medi-Cal program
Direct Regulation and Limitation of Hospital Prices Under Health Plan Commercial Contracts	Directly regulates provider prices under health plans serving a large commercially insured population (public employees)	Covers only one segment of fully insured population	Updating pricing regulations over time to account for other factors	California Workman's Compensation program

Source: Author review of state websites and interviews.

make health care more affordable for consumers and in part to reduce pressure on public and private purchasers of care.

Each state has different ways of accomplishing its goals: Maryland started with explicit controls on hospital budgets; Oregon initially focused on the total cost of care for Medicaid beneficiaries and public employees; Rhode Island measured and controlled the cost of care through regulation of health insurance premiums in the fully insured population; and Massachusetts monitored and set targets for the annual growth of total health care expenditures per capita across the entire population (Exhibit 12).

Exhibit 12. Statewide Spending Targets and Benchmarks

	SPENDING CATEGORIES	YEARS COVERED	SPENDING GROWTH TARGETS	SPENDING GROWTH TARGETS: DETAIL	BENCHMARKS
Maryland	Hospital spending	2018–22	3.6% per year + $300 million in Medicare savings	Hold all payer per resident hospital spending growth below 3.6% per year; generate at least $330 million in Medicare per capita hospital savings over five years.	3.6% benchmark equals 10-year average all-payer hospital growth in 2002–12; expected to be below state GSP growth per capita; Medicare savings tied to CMS waiver.
Massachusetts	Total health care spending by all payers	2012–17; 2018–22	3.6%; 3.1%	Health care cost benchmark for the first five years is 3.6%; for years 6–10, it's 3.1%.	First five years at 3.6%, equal to the state's projected PGSP. Established by state leadership with input from outside economists. Years 6–10, benchmark at PGSP minus 0.5% (3.1%). Gave HPC the authority to adjust up to 3.6%.
Oregon	Health insurance premiums & Medicaid spending	2017–present	3.4%	2017 law limits annual growth in Public Employee Health Plan premiums and Medicaid spending to no more than 3.4% and limits payments to in-network hospitals to 200% of the Medicare allowable; 2019 law established new Total Health Care Cost Growth Benchmark (HCCGB) program to set total cost benchmark starting in 2020.	Expanded Sustainable Total Health Care Cost Growth Benchmark program will apply to insurance companies, hospitals, and health care providers. Health care costs should not outpace wages or the state's economy and the program will also identify opportunities to reduce waste and inefficiency.
Rhode Island	Health insurance premiums	2019–22	3.2%	Currently, regulatory authority covers Medicaid and fully insured health plans; expanded benchmark covers THCE for all residents. A 2019 executive order sets the annual target at 3.2% for 2019–22.	Statewide target for 2019–22 equal to Rhode Island's per capita PGSP. PGSP formula for forecast growth in per capita: expected growth in national labor force productivity + expected growth in the state civilian labor force + expected national inflation – expected state population growth.

Notes: *CMS* is the Centers for Medicare & Medicaid Services. *GSP* is gross state product. *HPC* is the Health Policy Commission. *PGSP* is potential gross state product. *THCE* is total health care expenditures.

Source: Author review of state websites and interviews.

2. Define and Measure Affordability in the Context of Both Consumer and State Budget Spending.

All the states in this study set overall cost or premium growth targets. These targets combined expenditures by employers and health insurance plans with direct out-of-pocket expenditures by families. This kind of data aggregation ignores how the distribution of spending can vary and does not account for the possibility that global spending could be below the prescribed target but out-of-pocket spending by families could increase faster than the global target and economic or income growth rates.

Detailed data collected by the Massachusetts HPC illustrate this dynamic in Massachusetts. Between 2016 and 2018 the total median family compensation showed a substantial increase of $712 per month (compensation is defined to include both salary and health insurance contributions from employers). However, health insurance premiums, along with family out-of-pocket payments for services, also increased during this period ($277). As a result, increased health-related spending consumed almost 40% of the increase in total compensation (and when increased taxes are deducted from income growth, net take-home pay is reduced by more than 60%). And this was during a period when the state met its overall health spending growth targets.

Another aspect of affordability relates to the ability of states to finance health care program costs that are growing faster than state revenues and overall budgets. Health-related spending growth in all states, including California, has outpaced state-level economic growth, per capita income growth, and tax receipts. These trends raise the question of how state health care cost-containment commissions might include additional data collection and targets tied to projected state-level expenditures unrelated to health care and total state budget growth to track the spillover effect of increased health spending on other important state programs.

3. Create a Commission Structure with a Robust Level of Stakeholder Participation.

The four states reviewed in this report vary in terms of their commission structure and makeup. Rhode Island relies on the Commissioner of Health Insurance as the lead agency. Oregon establishes both governmental agencies and extensive working groups. Maryland has an independent commission that oversees its hospital global budgeting system. And Massachusetts has an independent commission that is made up entirely of health care experts and consumers. However, all four states rely heavily on participation from a broad range of stakeholders, including health industry representatives and consumer groups. All the states emphasize the importance of transparency in their work, cooperation and support from all stakeholders, and political consensus and buy-in from key stakeholders to design, implement, and sustain their cost-control programs. For example, Massachusetts mandates annual public hearings for all stakeholders, and Rhode Island recently completed a written pledge (Compact to Reduce Growth in Health Care Costs) committing health industry stakeholders to agreed-upon cost growth targets.

4. Ensure the Commission Has Access to Comprehensive Data.

The data landscape varies from state to state, but all the states studied recognize and emphasize the importance of having the right data to carry out their missions, and all the states hope to expand the data they collect to emulate the Massachusetts program. The HPC in Massachusetts has the most complete health care data system of any cost-containment commission in the country. HPC gathers data from all payers and providers to calculate total health care expenditures as well as to support extensive, detailed analyses of the underlying factors affecting growth in health spending. These analyses provide transparency, support program development, and generate buy-in from stakeholders for controlling spending.

But building a comprehensive data structure requires both regulations and voluntary cooperation from stakeholders. States can put in place reporting regulations and surveys that collect the data assembled under the comprehensive HPC model. However, federal law currently limits the ability of states to mandate reports of claims-level data for the self-insured commercial population, which represents approximately half of the commercially insured population in each state. States can mandate reporting of aggregate data for this population but not the claims-level data needed to support detailed analyses of underlying cost factors and to properly adjust for differences in patient and population characteristics.

5. Consider an Array of Enforcement Mechanisms.

All the states studied rely heavily on data reporting, analysis, and transparency to meet their targets. Additionally, each of the states takes different types of enforcement actions when growth in costs exceeds target rates. The HPC has two main mechanisms: First, the HPC can analyze changes in market structure, including mergers and other consolidations, and refer matters to the state attorney general for action; second, the HPC monitors annual spending growth rates for many reporting entities, including health providers and plans, and it can require remedial action and impose fines if it finds excessive growth.

Oregon controls overall Medicaid spending growth and can impose limits on payments to in-network hospitals of no more than 200% of the Medicare rate. Maryland enforces its program by controlling the total amount of revenue that each hospital receives based on its approved budget, and it sets rates to meet agreed-upon targets with the Centers for Medicare & Medicaid Services (CMS). The Commissioner of Health Insurance in Rhode Island can request and enforce reductions in proposed health insurance premiums for forthcoming years.

Conclusion

The idea of using independent, state-level commissions to control unnecessary health care spending is not new. Nor are the problems and pressures that excess health care spending presents to individuals, families, and state policymakers. This study has found that Maryland, Massachusetts, Oregon, and Rhode Island have taken varying approaches to developing independent regulatory agencies that monitor and enforce actions designed to reduce wasteful health spending.

A closer look at each of these models illustrates the complexities facing any state cost-containment commission. But with the right design, informed by the lessons learned from these examples, California and other states looking to adopt new cost-containment strategies have the potential to leapfrog ahead of other states and generate far-reaching impact toward the elusive goal of containing health spending.

Appendix A. Methodology

The research for this report analyzed information from multiple sources, including published papers, studies, and articles in the literature related to the health care cost-containment commissions in each state; publicly available presentations by state commissioners and/or staff; websites for each state, including laws, regulations, reports, policy documents, and public announcements; phone interviews with commissioners and/or senior staff from each state; and feedback from state staff related to descriptions of each state's program. Study participants included these:

	INTERVIEWEE	POSITION
Maryland	Robert Murray, MA, MBA	Former Executive Director, Maryland Health Services Cost Review Commission (HSCRC)
	Joe Antos, PhD	Vice-Chair, HSCRC
Massachusetts	David Seltz	Executive Director, Massachusetts Health Policy Commission (HPC)
	David Auerbach, PhD	Senior Director for Research and Cost Trends, HPC
Oregon	Jeffrey Scroggin	Policy Advisor, Oregon Health Authority (OHA)
	Zachary Goldman, MPP	Economic Policy Advisor, OHA
Rhode Island	Marie L. Ganim, PhD	Commissioner, Office of the Health Insurance Commissioner (OHIC)
	Cory King, MPP	Director of Policy, OHIC

Appendix B. An Overview of State Cost-Containment Commissions

Massachusetts Health Policy Commission

In 2012, Massachusetts established the Health Policy Commission (HPC) to set statewide targets for reducing health care spending growth. The spending target is comprehensive and covers all payers (both public and private) and total health care expenditures (THCE) — including all medical expenses, non-claims-related payments, patient out-of-pocket expenses, and the net cost of private insurance. Massachusetts policymakers initially considered a regulated approach similar to Maryland's statewide hospital rate-setting model, but ultimately adopted a model that relies on the private market rather than regulations to set rates and influence spending.

The commission is designed to improve system transparency and ultimately improve the health care market's performance through the following actions: conducting applied research, preparing reports and convening stakeholders, adopting a statewide THCE growth target, monitoring market performance and compliance with the target, and working with organizations to advance innovation. The commission is supported by a sister agency, the Center for Health Information and Analysis (CHIA), which is responsible for all data collection and selected analyses and reporting.

While largely a transparency-oriented model, mandated reporting requirements are in place for health care organizations to provide market oversight and enforcement. If an individual provider organization exceeds specified benchmarks, it is put on a list, referred to the HPC, and may be required to file a performance improvement plan. The law governing the commission also requires health care organizations to increase the adoption of alternative payment models, including value-based models.

The Massachusetts model calls for broad involvement of stakeholders, including providers, health plans, and the public. A key part of the transparency and public accountability process involves an annual hearing over a two-day period at which health care organizations testify under oath. Implicit in this approach is that increased transparency will spur provider organizations to change their financial goals and performance. In general, health plans, providers, and hospitals have broadly supported the benchmark growth rate for costs. Health plans incorporate the benchmark into their contract negotiations with providers, including hospitals.

Hospital spending growth has slowed in the state since the HPC was established. During the commission's first five years, the state experienced annual cost growth of 3.44%, slightly below the target rate of 3.6%, including even lower growth for hospital costs. Data for the most recent year show even slower growth in costs to meet the new lower target of 3.1%. Growth in costs has been contained in settings such as acute care hospitals.

Maryland Health Services Cost Review Commission

Maryland state officials, with input from Maryland health care leaders, negotiated a new agreement with the federal government to extend its hospital-based model to include all care for Maryland's Medicare enrollees under its Health Services Cost Review Commission (HSCRC). The commission adopted a new model (total cost of care, or TCOC) in 2019 and has a 10-year term during which Maryland must meet agreed-upon performance requirements. During the term, the state can develop flexible payment programs that encourage providers to improve health and the quality of care while at the same time keeping growth in Medicare spending below the national growth rate. The TCOC model encourages value-based health care redesign and provides new tools and resources for primary care providers to better meet the needs of patients with complex and chronic conditions as well as to achieve better health for all Maryland residents. The TCOC model is designed to move the state from its initial inpatient hospital rate-setting approach to a more comprehensive population-based health model that includes both inpatient and outpatient costs.

Key elements of the model include the following:

- Hospital cost growth per capita for all payers must not exceed 3.58% per year. The state can adjust this growth limit based on economic conditions, subject to federal review and approval.
- The state expects to generate savings of $300 million in annual total Medicare spending for Medicare Part A and Part B by the end of 2023.
- A state commission sets and enforces quality of care and population health goals.
- Federal resources can be invested in primary care and delivery system innovations to improve chronic care and population health, as well as resources and systems to help physicians and other providers improve care and care coordination.
- Incentive programs reward population health and encourage participation in voluntary value-based care programs.
- The state cannot regulate Medicare and private fee schedules for physicians and clinicians.

Rhode Island Office of the Health Insurance Commissioner

In 2004, Rhode Island became the first state to establish a commission that conducts rate reviews for health insurance plans, known as the Office of the Health Insurance Commissioner (OHIC). The commissioner, citing the broad statutory language that created OHIC, expanded the focus of OHIC in 2009 to mandate that insurers spend one percentage point more in total spending on primary care for five years, expand a statewide multipayer medical home program to better manage care for those with diabetes and chronic conditions, expand the use of electronic medical records to reduce unnecessary utilization and to identify high-risk patients, and reform payment systems to provide incentives for quality.

In 2010, Rhode Island formally adopted affordability standards to promote expanded goals that include the development of a patient-centered medical home system to expand primary care, reduce costs, and increase adoption of payment reform strategies. Strategies include promoting population-based contracting, adopting alternative payment methods, improving hospital contracting practices, and controlling cost increases associated with population-based contracts. In 2018, Rhode Island established its Working Group on Healthcare Innovation to develop recommendations for establishing a global health spending cap for Rhode Island, linking a large proportion of health care payments (80%) directly with quality, developing a more standardized health information technology system for all payers, and establishing performance frameworks to achieve population health and wellness goals. The state also formed the Working Group to Reinvent Medicaid to develop recommendations for regulations that improve system performance, generate state budget savings, and form a statewide health information exchange, including an all-payer claims database.

Oregon Health Policy Board

In 2009, the Oregon Legislature created the Oregon Health Policy Board (OHPB) to help align policies that affect the broader health care system. The board consists of eight members nominated by the governor and approved by the state senate. The OHPB oversees the Oregon Health Authority (OHA), which is responsible for state health care transformation programs.

The OHPB established working groups focused on metrics and scoring for coordinated care organizations (CCO), including growth in total costs. CCOs are networks of health care providers — physical health care, behavioral health care, and sometimes dental care providers — who have agreed to work together to serve people in their communities who receive health care coverage under the Oregon Health Plan (Medicaid). In 2012, Oregon received a CMS 1115 waiver to establish a coordinated care strategy that allows the state to set specific cost growth targets for Medicaid and to invest a portion of savings in new care models, including an expansion of CCOs. CMS extended the waiver through 2022. The plan caps Medicaid cost growth at 3.4% per year.

The OHPB also works to establish a baseline for sustainable health expenditures and to develop potential measures beyond Medicaid. An all-payer, all-claims technical advisory group focuses on enhanced data resources on total cost. In 2019, the Oregon Legislature laid the groundwork for developing a health spending target for the entire state population. The law established the Sustainable Health Care Cost Growth Target program and mandated that the OHA — in collaboration with the Department of Consumer and Business Services, the OHPB, and an implementation committee of consumers and stakeholders — develop a statewide spending growth target and recommendations to the assembly in 2020 for instituting a benchmark to contain the growth of health spending.

Endnotes

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2. "Commercial Insurance: Where You Live Determines What Health Care You Get and How Much You Pay," Integrated Healthcare Assn., 2015, accessed December 13, 2019.
3. Liz Hamel, Calley Muñana, and Mollyann Brody, "Kaiser Family Foundation/LA Times Survey of Adults with Employer-Sponsored Insurance," Kaiser Family Foundation, May 2019.
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7. "HPD Review Committee," Office of Statewide Health Planning and Development, n.d.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: March 4, 2020

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: Sterile Compounding Next Steps

SUMMARY

On June 1, 2019, USP published revisions to Pharmaceutical Compounding –, <797> Nonsterile Preparations and Pharmaceutical Compounding – Sterile Preparations, as well as new chapter, <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging. After publication of the revised and new compounding standards, USP received appeals on certain provisions in, <795>, <797> and <825>. In accordance with USP's Bylaws, the responsible Expert Committees worked with a sense of urgency to consider the information raised in the appeals and issued decisions on the appeals (see Decisions on Appeals to USP). In accordance with USP's formal appeals process, stakeholders who submitted appeals to the compounding chapters had the opportunity to request further review by an appointed Panel, and USP has received four (4) such requests. The issues under further review are related to: ` Beyond-Use Date (BUD) provisions in <795> and <797> and ` Framework and BUD provisions in <825>. USP's Bylaws provide that the official date of a standard under appeal must be postponed while an appeal is pending. Therefore, USP is postponing the official dates of the revised<795> and, <797> and the new general chapter <825> until further notice. The decisions on the appeals to<795>, <797>, and <825> do not foreclose the possibility of future revisions to these chapters.

The appeals hearings occurred on January 21, 2020, and January 22, 2020. After due deliberation the Appeals Panel will either, 1) deny the appeals, resulting in the standards approved by the Expert Committee becoming official (with at least another six-month implementation period being granted); or 2), grant one or more of the appeals, resulting in a remand of the standards to the responsible Expert Committee for further evaluation, stakeholder engagement, and or revisions.

DISCUSSION

1. What is the state of sterile compounding activities at this point across the state?
2. What should we expect and or focus on until next steps from USP?
3. Without further review from Cal OSHA, where are hospitals with implementation of <USP 800>?
4. What policies are being implemented at the bedside, and in ambulatory areas relative to sterile compounding?
5. Is there any activity CHA needs to be engaged in at this point?

Attachment: USP FAQs on the Compounding Appeals

BJB:br

FAQs on the Compounding Appeals

Appeals Status

1. Which USP Compounding Chapters are being postponed?

Three USP Compounding Chapters are being postponed until further notice pending the resolution of the appeals:

1. Revised <795> *Pharmaceutical Compounding – Nonsterile Preparations*
2. Revised <797> *Pharmaceutical Compounding – Sterile Preparations*
3. New chapter <825> *Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*

2. Which USP Compounding Chapters are currently official?

The current official chapters are <795> (last revised in 2014) and <797> (last revised in 2008). Download here.

General Chapter <800> is not subject to any pending appeals and will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable. USP encourages utilization of <800> in the interest of advancing public health.

USP plays no role in enforcement. State and other regulators may make their own determinations regarding the enforceability of <800>.

3. Why is the official date of the new and revised USP General Chapters <795>, <797>, and <825> (published on June 1, 2019) being postponed?

On June 1, 2019, USP published revisions to <795> *Pharmaceutical Compounding – Nonsterile Preparations* and <797> *Pharmaceutical Compounding – Sterile Preparations*, as well as new chapter <825> *Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*. After publication of the revised and new compounding standards, USP received appeals on certain provisions in <795>, <797>, and <825>.

In accordance with USP's Bylaws, the responsible Expert Committees worked with a sense of urgency to consider the information raised in the appeals and issued decisions on the appeals (see Decisions on Appeals to USP <795> and <797> and <825>). In accordance with USP's formal appeals process, stakeholders who submitted appeals to the compounding chapters had the opportunity to request further review by an appointed Panel, and USP has received four (4) such requests.

The issues under further review are related to:

- Beyond-Use Date (BUD) provisions in <795> and <797>
- Framework and BUD provisions in <825>

USP's Bylaws provide that the official date of a standard under appeal must be postponed while an appeal is pending. Therefore, USP is **postponing the official dates of the revised <795> and <797>, and the new general chapter <825> until further notice**.

The decisions on the appeals to <795>, <797>, and <825> do not foreclose the possibility of future revisions to these chapters.

4. When are the new and revised compounding standards for USP General Chapters <795>, <797>, and <825> (published on June 1, 2019) expected to become official?

The official dates of <795>, <797>, and <825> will be postponed until further notice pending resolution of the appeals.

At this time, USP cannot predict or project a future official date for any of these chapters as the appeals process remains active. Regardless of the outcome of the appeals process, USP would not reestablish an official date for chapters <795>, <797>, or <825> without granting another six-month implementation period, at a minimum.

Any anticipated dates offered by third parties are not accurate as the appeals process is currently ongoing. USP is committed to communicate updates on the compounding chapters and appeals process.

5. What sections, or provisions, in USP General Chapters <795>, <797>, and <825> are being appealed?

First Level of Appeals

After the revisions were published on June 1, 2019, USP received appeals on key topics covered in USP <795>, <797>, and <825> including:

- Beyond-Use Date (BUD) provisions in <795>, <797>, and <825>
- Removal of Alternative Technology provision from <797>
- Applicability of <795> and <797> to veterinary practitioners
- Compounding from sterile substances in <825>
- Applicability of <825> within the radiopharmaceutical regulatory context

Regarding <795> and <797>, the Compounding Expert Committee (EC) reviewed the appeals, deliberated on the information related to <795> and <797> at an EC meeting on August 8, 2019, and issued decisions on all appeals on August 16, 2019. For a summary, see *Decision on Appeals to <795> and <797>* (Aug. 16, 2019). Regarding <825>, the Chemical Medicines Monographs 4 EC reviewed the appeal, deliberated on the information related to <825> at an EC meeting on August 15, 2019, and issued its decision on August 19, 2019. For a summary, see *Decision on Appeals to <825>* (September 13, 2019).

Second Level of Appeals

In accordance with USP's formal appeals process, stakeholders who submitted appeals to the compounding chapters had the opportunity to request further review by an appointed Panel, and USP has received four (4) such requests.

The issues under further review are related to:

- Beyond-Use Date (BUD) provisions in <795> and <797>
- Framework and BUD provisions in <825>

6. What is the composition of the Appeals Panel that will adjudicate the second-level appeals to <795>, <797>, and <825>?

The members of the Appeals Panel are:

- Jesse L. Goodman, M.D., M.P.H., President, USP Convention
- Mary Foster, Pharm.D., Council of Experts
- Dennis K.J. Gorecki, B.S.P., Ph.D., Council of Experts
- Amy J. Karren, B.Sc., Council of Experts

- Timothy R. Franson, B.S. Pharm., M.D., Board of Trustees
- Marilyn K. Speedie, Ph.D., Board of Trustees
- Thomas R. Temple, B.S.Pharm., M.S., FAPhA, Board of Trustees

The members of the Appeals Panel will maintain strict confidentiality in connection with their adjudication of the appeals. Any questions about the appeals process should be directed to USP staff by email at execsec@usp.org.

7. When will USP hold hearings on the appeals?

USP has scheduled hearings for the appeals to <795>, <797>, and <825> at the following dates and times:

Tuesday, January 21
9 a.m. to 12 p.m.

Public hearing on <795> and <797>

- Appellants: Civic Center Pharmacy, Reed's Compounding Pharmacy, Camelback Compounding, Nationwide Compounding, White Mountain Pharmacy, Mountainview Pharmacy, Mixtures Pharmacy, Potter's House Apothecary, Raintree Apothecary, Mortar and Pestle Pharmacy, Community Clinical Pharmacy, Melrose Pharmacy, Rosy's Pharmacy, Prescription Lab Pharmacy, Acacia Pharmacy, MedMetrics Pharmacy, Strive Pharmacy, The Compounders Group (TCG)

1:30 to 4:30 p.m.

Public hearing on <825>

- Appellant: Fagron

Wednesday, January 22
9 a.m. to 12 p.m.

Public hearing on <795> and <797>

- Appellants: Alliance for Pharmacy Compounding, Innovation Compounding, and Wedgewood Village Pharmacy

1:30 to 4:30 p.m.

Closed hearing on <795> and <797> **[Hearing closed to public based on appellants' request for confidential treatment]**

- Appellants: Five unnamed compounding pharmacies

The following is the agenda for each hearing:

- Administrative Opening Procedures (5-10 min.) – USP Legal
- Opening Remarks (5-10 min.) – Chair of Appeals Panel
- Appellants' presentation (2 hours) – Appellants
- Panel Opportunity to Ask Questions of Appellants (30 min.) – USP Appeals Panel
- Administrative Closing Procedures (5-10 min.) – USP Legal

For appeals that are open to the public, observers may register to attend at the following link: https://www.cvent.com/events/usp-appeals-hearings/agenda-23ea44ef32a14ab18fc3f547fcc62811.aspx. Observers must register at least five business days prior to the hearing. Space for observers is limited, and USP will make every effort to equitably distribute the openings for those observers seeking to attend in person. Attendance by WebEx is an option. Observers will not be permitted to speak or otherwise participate in the hearing.

8. What decisions can the Appeals Panel make with respect to the appeals?

Under Section 7.06(a) of USP's Rules and Procedures of the Council of Experts, new or revised documentary standards "must be voted on and approved by the responsible Expert Committee." The Appeals Panel is not the Expert Committee responsible for USP <795>, <797>, and <825>. Thus, the Appeals Panel is not authorized to revise the text or substance of the standards under appeal. For this reason, after due deliberation the Appeals Panel will either: (1) deny the appeals, resulting in the standards approved by the Expert Committee becoming official (with at least another six-month implementation period being granted); or (2) grant one or more of the appeals, resulting in a remand of the standards to the responsible Expert Committee for further evaluation, stakeholder engagement, and/or revisions.

USP Standard-Setting and Appeals Process

9. How does the USP standard-setting process work?

When it comes to the development and maintenance of quality standards, USP believes public input is critical to ensuring our standards have the intended effects of advancing quality and reducing patient risk. This is why USP has a robust standard setting process:

1. **Public Health Need:** USP – independently or with help from stakeholders – identifies a public health need and evaluates opportunities for possible standard development.
2. **Draft Standard:** USP convenes a committee of independent experts that are knowledgeable on the public health issue to develop the standard.
3. **Public Comment Period:** The draft standard is published for stakeholder input. USP actively seeks engagement with stakeholders throughout the standard-setting process through stakeholder meetings, advisory roundtables, and open-microphone webinars.
4. **Review and Approval:** Comments are evaluated and addressed. If needed, further revisions and comments and considered.
5. **Publication:** The final standard is published with an official date typically at least 6 months after publication.

For more information on USP's standard-setting process, please visit:

- Healthcare Quality & Safety Standard-Setting Process
- Quality Matters Blog: Quality Standards that Combine Science, Expertise, and Experience to Protect Patients and Healthcare Workers

10. How can I provide comment to a standard?

There are multiple ways to contribute. Stakeholders can submit comments on USP standards or take part in one of our Expert Committees. USP welcomes stakeholder involvement in the standard setting process through the 2020–2025 Call for Candidates. USP's public standards are in continuous revision, and the Expert Committees are committed to ongoing engagement with stakeholders to develop additional resources.

11. How does the USP appeals process work?

USP has an established process by which any interested party may appeal a published standard:

1. An appeal is considered timely if submitted within 60 days of a standard's publication date. USP requests that submitters include relevant information, including supporting data, context, and the basis for the appeal.

2. The responsible Expert Committee (EC) reviews the appeal(s) and has 90 days to issue a decision.
3. Following the EC's decision, the appellant(s) has/have 30 days to request further review by a panel consisting of three members of the Council of Experts appointed by the Chair, three members of the Board of Trustees appointed by the Chair of the Board, and up to three additional experts appointed by the President of the Convention in consultation with the Chair of the Council of Experts. The panel is chaired by the President of the Convention.
4. The panel is convened within 90 days of the request for an appeal, and the appellants are given the right to appear at a hearing of the panel. The panel's decision is final.

Compendial Applicability and Official Chapters

12. Is General Chapter <800> being postponed?

General Chapter <800> is not being postponed because it is not subject to any pending appeals and became official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable. USP encourages utilization of <800> in the interest of advancing public health and has published additional information on the context for implementation of this chapter.

13. What does "compendially applicable" mean?

The USP is an official compendium of the U.S., and USP standards are therefore considered "compendial standards."

USP General Notices and Requirements section 3.10 describes the applicability of standards. A general chapter numbered below 1000 becomes compendially applicable and is considered a required standard when:

- The chapter is referenced in a monograph,
- The chapter is referenced in another general chapter below 1000, or
- The chapter is referenced in General Notices.

Because chapter <800> is not referenced in an official chapter nor in the General Notices, it is not compendially applicable.

States and other regulators with jurisdiction, may integrate <800> into their statutes and regulations, or through other steps in accordance with their own policy making processes, to apply and enforce <800> in their jurisdictions.

14. Does USP enforce standards?

USP plays no role in enforcement. State and other regulators may make their own determinations regarding enforceability of USP standards. USP remains committed to advancing public health and to promoting the quality of compounded preparations and the safe handling of hazardous drugs. USP will continue to communicate updates on the compounding chapters and the appeals process.

15. Can facilities early adopt the revised (postponed) USP compounding standards while they remain under appeal?

While the postponements of the revisions to <795> and <797> are in place, the currently official chapters of <795> (last revised in 2014) and <797> (last revised in 2008), including the section *Radiopharmaceuticals as CSPs*, remain official. The decisions on the appeals to <795>, <797>, and <825> do not foreclose the possibility of revisions to these chapters.

From a compendial perspective, early adoption of revised standards in advance of the official date is permitted unless

specified otherwise at the time of publication (USP General Notices 3.10). At the time of publication, USP did not prohibit early adoption.

> *3.10, Applicability of Standards:*
>
> *Early adoption of revised standards in advance of the official date is allowed by USP unless specified otherwise at the time of publication. Where revised standards for an existing article have been published as final approved "official text" (as approved in section 2.10 Official Text) but have not yet reached the official date (6 months after publication, unless otherwise specified; see "official date", section 2.20 Official Articles), compliance with the revised standard shall not preclude a finding or indication of conformance with compendial standards, unless USP specifies otherwise by prohibiting early adoption in a particular standard.*

States, regulators, and accreditation bodies may make their own determination on implementation and enforcement of the currently official or revised (postponed) USP compounding standards. Stakeholders should speak with the appropriate regulators in their state to determine what may be required.

16. UPDATED: How can facilities implement <800> in light of conflicts with provisions in currently official <797>?

For facilities that implement <800>, there are two sections that are not harmonized between the currently official <797> and <800>: 1) Segregated Compounding Area and 2) "Low volume" hazardous drug (HD) compounding. Below we point out the differences between USP <800> and currently official <797>. States, regulators, and accreditation bodies may make their own determination on implementation and enforcement of USP standards. Stakeholders should speak with the appropriate regulators in their state to determine what may be required.

1. **Segregated Compounding Area (SCA)**

- Currently official USP <797> only allows low-risk level nonhazardous and radiopharmaceutical Compounded Sterile Preparations (CSPs) with 12 hour or less beyond-use date (BUD) to be prepared in an unclassified segregated compounding area.
- USP <800> allows low and medium risk level hazardous drug CSPs to be prepared in an unclassified containment segregated compounding area (C-SCA). The C-SCA is required to have fixed walls, be externally vented with 12 air changes per hour (ACPH), and have a negative pressure between 0.01 and 0.03 inches of water column relative to the adjacent areas.
- Note the differences in terminology and requirements in the SCA in currently official USP <797> and C-SCA in <800>.
  - Under <800>, low- and medium-risk level HDs may be prepared in a C-SCA provided it meets the requirements in <800> and the CSP is assigned a BUD of 12 hours or less.
  - If not implementing <800>, only low-risk level nonhazardous and radiopharmaceutical CSPs with 12 hour or less BUD may be prepared in a SCA (as described in <797>).

2. **"Low volume" hazardous drug compounding**

- Currently official USP <797> allows facilities that prepare a "low volume" of HDs to compound these drugs in a non-negative pressure room if "two tiers of containment (e.g., closed system transfer device (CSTD) within a biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI) that is located in a non-negative pressure room)" are used.
- USP <800> requires facilities that prepare HDs to have a containment secondary engineering control (C-SEC) that is externally vented, physically separated, have appropriate air exchange, and have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.
- Under <800>, HDs must be prepared in a C-SEC meeting the requirements in <800>.
- If not implementing <800>, facilities preparing a low volume of HDs may continue to compound these CSPs outside a

negative pressure room if two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) are used.

17. Given that the revised USP <795> and <797> and new chapter <825> are postponed until further notice, will the currently official chapters be available for free digitally? What about USP <800>?

Yes, you can download the currently official and postponed chapters at: http://go.usp.org/l/323321/2019-05-31/2dfgwl.

Please keep in mind that individual chapters are not sufficient for a comprehensive approach to pharmaceutical compounding. Additional chapters are required for complete implementation; see USP Compounding Compendium or USP-NF.

Resources

- NITR Announcing Postponement
- Download USP compounding standards
- USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
- USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
- USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings
- USP General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging
- Summary of updates for the new and revised (postponed) General Chapters <795>, <797>, and <825>
- Beyond-use dates (BUDs) for the revised (postponed) General Chapters <795> and <797>

For any questions, contact USP's Healthcare Quality & Safety Team at CompoundingSL@usp.org.Yes, you can download the currently official and postponed chapters at: http://go.usp.org/l/323321/2019-05-31/2dfgwl.

Please keep in mind that individual chapters are not sufficient for a comprehensive approach to pharmaceutical compounding. Additional chapters are required for complete implementation; see USP Compounding Compendium or USP-NF.

Resources

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For any questions, contact USP's Healthcare Quality & Safety Team at CompoundingSL@usp.org.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: March 4, 2020

TO: Medication Safety Committee Members

FROM: Candace Fong, Pharm D, System VP Medication Safety, CommonSpirit Health

SUBJECT: Schedule II Controlled Substance Reconciliation of the Automatic Dispensing Cabinets, 1715.65

SUMMARY

There has been continued confusion regarding the requirements under 1715.65. Inventory Reconciliation Report of Controlled Substances as it relates to the "physical" counts. Some board surveyors interpret the regulation to include the automated dispensing cabinets. Below is the information received from the Board of Pharmacy.

On December 19th, 2019, the Board of Pharmacy revealed (through an email) that it was in the process of reconsidering regulation requirements. During the November Board Meeting, the board directed the committee to continue its reassessment of the regulation. At the same time, the board emphasized that proposed amendments related to ADD machines reflect the current policy. See below

(h) The pharmacist-in-charge of an inpatient hospital pharmacy, *using an ADDS shall not be required to perform physical counts of the inventory as required in (c) (1) but shall be required to fulfill all other inventory reconciliation reporting requirements.* ~~Or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:~~

~~(1) All controlled substances added to an automated drug delivery system are accounted for:~~

~~(2) Access to automated drug delivery systems is limited to authorized facility personnel:~~

~~(3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and~~

~~(4) Confirmed losses of controlled substances are reported to the board.~~

DISCUSSION

1. Is the reply stating that this regulatory change will be submitted and or that the Board of Pharmacy interprets the present regulation as covering the ability for hospitals to forgo the counting of Controlled Substances from ADDs?
2. What next steps does CHA need to take?

BJB:br

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: March 4, 2020

TO: Medication Safety Committee Members

FROM: Rita Shane, PharmD, FASHP, FCSHP, Chief Pharmacy Officer and Professor of Medicine, Cedars-Sinai Medical Center
BJ Bartleson, RN, MS, NEA-BC, VP Nursing and Clinical Services

SUBJECT: Biosimilars

SUMMARY

Biosimilars have been a hot topic since the fall of 2018, when Rita Shane raised the initial concerns with Aetna's designation of Fulphila as the preferred biosimilar for cancer patients. Since that time, continued payer rebate activity and increased numbers of new biosimilars have raised the issue to an even more important patient quality of care level. Rita had drafted legislation to be carried by Senate member Stone, however, due to his departure, and lastminute approach with other authors, no legislators were willing to carry the bill his year. CHA also had concerns about sponsoring the bill due to higher priorities and resource allocation necessary to carry the bill.

Attached are: 1) the draft language of a biosimilar bill, 2) Rita's latest SBAR, and 3) CHA's Medication Safety Committee Biosimilar History and Workplan.

The CHA Medication Safety Committee has been instrumental in moving policy issues forward.

DISCUSSION

1. Do members continue to see this as a hot topic that we need to move forward?
2. Is the biosimilar issue only occurring in the outpatient space, or is there potential for this to move into the inpatient arena with additional biosimilars?
3. What physician groups are you working with who see this of concern?
4. What next steps would you propose?

Attachments: Biosimilar SB
Biosimilar Summary: Risks and Recommendations
Health Plan Designation of Preferred Biosimilars Work Plan
Preferred Biosimilars Across Payers
Payer Strategies and Implications
FDA Approved Biosimilars and Uses

BJB:br

AUTHOR'S COPY

An act to add Section 1367.245 to the Health and Safety Code, and to add Section 10123.1971 to the Insurance Code, relating to health care coverage.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1367.245 is added to the Health and Safety Code, to read:

1367.245. (a) A health care service plan contract, including a specialized health care service plan contract, issued, amended, or renewed on or after January 1, 2021, that provides prescription drug benefits and provides coverage for a biological product, as defined in paragraph (1) of subdivision (j) of Section 4073.5 of the Business and Professions Code, shall also provide coverage for any biological product that is interchangeable, as defined in paragraph (2) of subdivision (j) of Section 4073.5 of the Business and Professions Code.

(b) A health care service plan subject to this section shall not subject a physician-administered interchangeable biological product that is medically necessary to prior authorization or step therapy. This applies both to interchangeable biological products covered under an enrollee's outpatient prescription drug benefit and to interchangeable biological products covered under an enrollee's medical benefit.

(c) "Physician-administered drug" means any legend drug, nonlegend drug, or vaccine administered or dispensed to a patient by a provider other than a pharmacy provider. Physician-administered drugs include prescribed biological products and interchangeable biological products, which are administered by a health care provider in a provider's office, hospital, clinic, or other health care facility setting.

SEC. 2. Section 10123.1971 is added to the Insurance Code, to read:

10123.1971. (a) A health insurance policy, including a specialized health insurance policy, issued, amended, or renewed on or after January 1, 2021, that provides prescription drug benefits and provides coverage for a biological product, as defined in paragraph (1) of subdivision (j) of Section 4073.5 of the Business and Professions Code, shall also provide coverage for any biological product that is interchangeable, as defined in paragraph (2) of subdivision (j) of Section 4073.5 of the Business and Professions Code.

(b) A health insurer subject to this section shall not subject a physician-administered interchangeable biological product that is medically necessary to prior authorization or step therapy. This applies both to interchangeable biological products covered under an enrollee's outpatient prescription drug benefit and to interchangeable biological products covered under an enrollee's medical benefit.

(c) "Physician-administered drug" means any legend drug, nonlegend drug, or vaccine administered or dispensed to a patient by a provider other than a pharmacy provider. Physician-administered drugs include prescribed biological products and interchangeable biological products, which are administered by a health care provider in a provider's office, hospital, clinic, or other health care facility setting.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Biosimilar Summary: Risks and Recommendations

Background: There are 574 biosimilars for cancer[1] in the pipeline and as of December 2019, there are 25 FDA-approved biosimilars of which the majority are for cancer patients. Pharmaceutical company rebate-driven insurance requirements are specifying which treatments patients can receive creating significant complexity and putting cancer patients at risk for medication errors. For intravenous chemotherapy, there are currently 57 checks are performed.[2]

Trastuzumab, a key drug used for breast cancer has 5 biosimilars and pegfilgrastim used to prevent life-threatening infections in cancer patients has 3 biosimilars. By using rebates, each of the 8 companies who make these 2 drugs can secure insurer *preferred* status creating a new paradigm for treatment. Besides prescribing the most effective chemotherapy regimen, physicians will need to verify that the drugs are correct based on the patient's insurance.

For these 2 drugs, cancer clinics will need to stock 11 products (with varying amounts per vial) vs 4 increasing the risk of mixups since biosimilars look-alike and sound-alike. Clinicians will need to ensure insurance-specific drugs are prepared, dispensed and administered correctly. If the clinic doesn't have the required drug(s) available, treatment will be delayed which with pegfilgrastim can be life-threatening. Imagine 4 people ordering steak at a restaurant requiring that each steak is sourced from a different beef producer as a condition of paying for the meal.

Example: Aetna has designated Fulphila® as the preferred biosimilar for cancer patients who are at risk for a low white blood count leading to hospitalization due to risk of life-threatening infections.

Assessment: Biosimilar drugs are considered therapeutically equivalent, however, because they are made from living organisms, there is a risk of an immune reaction if patients are switched from one product to another.

The decision-making authority for which drugs are used for hospital patients are defined by regulatory agencies as part of the formulary process as described in Table 1.

Patient Safety Issues

- The majority of approved biosimilars are for treatment of cancer patients where complex ordering and checking processes are in place to prevent life-threatening errors which have occurred in the past.

- As more biosimilars become available, there will be a significant increase in the number of lookalike/soundalike drugs in the electronic health record increasing the chance for errors.

- A requirement to have a specific biosimilar available based on the patient's health plan would increase workload for physicians, nurses and pharmacists in order to procure, maintain separate inventory, prescribe, label and dispense the "right payer-specific biosimilar" to the patient and correctly bill the health plan. If this became the standard, given the number of biosimilars which will be available, these additional steps significantly increase the risk of harmful medication errors by adding more complexity to medication management processes-see Table 2

Patient Out of Pocket Costs

- Since each biosimilar has a different code for billing, if there is a mixup of drugs, and the payer-specific biosimilar is not the one that is given, the payer would deny the payment and the patient would be responsible for paying the full cost of the medication.

Recommendations: Prohibit health plans from specifying which biologic products, including biosimilars, are to be administered in health-systems and by physician clinic settings to prevent harm in patients with cancer and other complex diseases and conditions

As biosimilars become commercially available, the health-systems will determine which medication will be used based on the evaluation by the Pharmacy and Therapeutics Committee. Using a similar approach, providers will conduct evaluations of available biologics and make determinations for their respective clinics. This P&T Committee's responsibility for formulary decision-making is required by CMS, The Joint Commission and the California Department of Public Health. Reimbursement by the payer should be equivalent to the reimbursement rate for the product regardless of which product is used, e.g. the innovator product or a biosimilar.

Summary

Rebate-driven insurance requirements by drug manufacturers not only increase healthcare costs, they also increase the risk of harm to vulnerable patients.

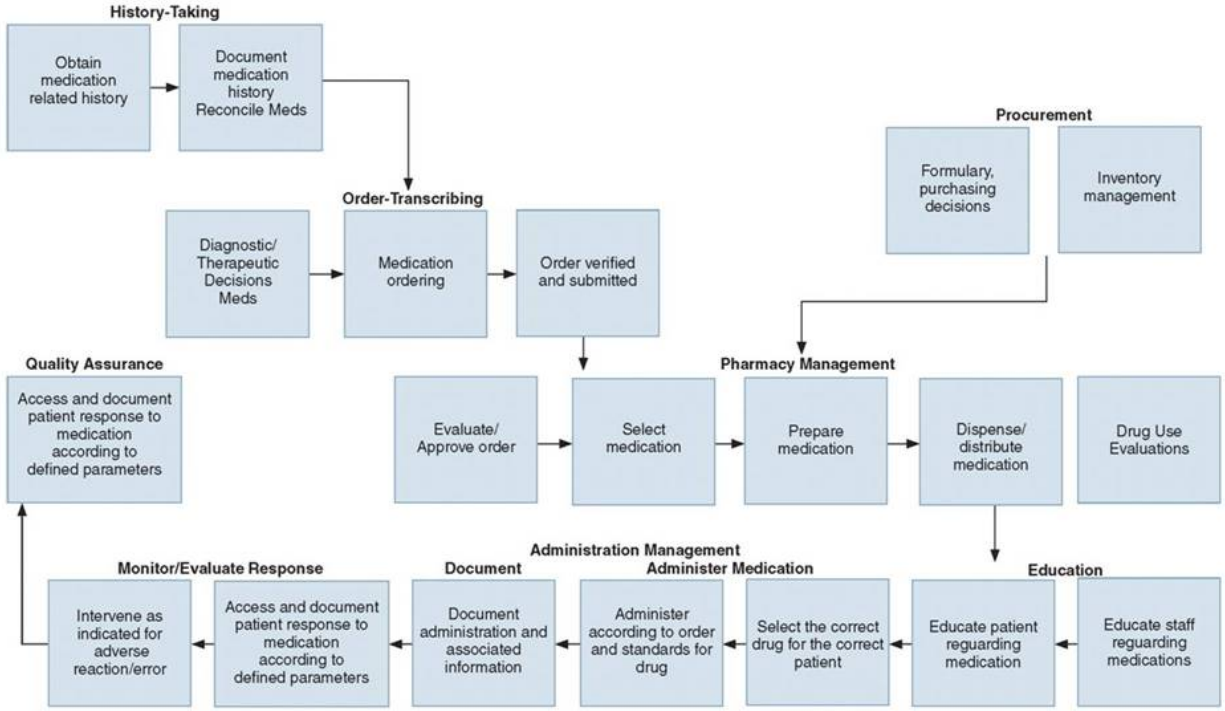
1. https://www.biosimilardevelopment.com/doc/biosimilars-pipeline-shows-remarkable-sustained-growth-0001, accessed 1/20/20.
2. https://ascopubs.org/doi/full/10.1200/JOP.2015.005892, accessed 1/20/20.

Table 1
Decision-Making Authority for Medications in Health-Systems

Regulatory Agency	Regulatory Reference	Regulatory Language
The Joint Commission (TJC)	MM.02.01.01	• Members of the medical staff, licensed independent practitioners, pharmacists, and staff involved in ordering, dispensing, administering, and/or monitoring the effects of medications develop written criteria for determining which medications are available for dispensing or administering to patients. Note: This element of performance is also applicable to sample medications. • The hospital maintains a formulary, including medication strength and dosage. Note 1: Sample medications are not required to be on the formulary. Note 2: In some settings, the term "list of medications available for use" is used instead of "formulary." The terms are synonymous.
The Centers of	482.25(b)(9)	A formulary system must be established by the medical staff to

Regulatory Agency	Regulatory Reference	Regulatory Language
Medicare and Medicaid Services (CMS) conditions of participation		assure quality pharmaceuticals at reasonable costs
The California Department of Public Health (CDPH)	Title 22 – 70263(c)	(c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or her representative and the administrator or his representative. (1) The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. (2) **The committee shall be responsible for the development and maintenance of a formulary of drugs for use throughout the hospital**.

Table 2 Medication Use Process



Health Plan Designation of Preferred Biosimilars Work Plan

CHA Medication Safety Biosimilar History

Overview of Issue:

Fall of 2018

In fall 2018, Rita Shane, PharmD, FASHP, FCSHP, from Cedars-Sinai Medical Center, raised concerns with Aetna's recent designation of Fulphila as the preferred biosimilar for cancer patients who are at risk for febrile neutropenia (low white blood count leading to hospitalization due to risk of life-threatening infections).

Specific Concerns:

- Biosimilar drugs are considered therapeutically equivalent, however, because they are made from living organisms, there is a risk of an immune reaction if patients are switched from one product to another. Therefore, the decision should be under the purview of the medical staff to ensure the safety of the medication prescribed. The interchangeability of a product is for a clinician to determine.
- While plans routinely choose preferred drugs related to self-administered drugs in the outpatient setting, once a patient is admitted into a hospital, the formulary is determined by the hospital or health system. The decision-making authority for which drugs are used for hospital patients are defined by regulatory agencies (The Joint Commission, CMS Conditions of Participation, CDPH). More specifically, the selection of drugs in a hospital setting is under the purview of a hospital's Pharmacy and Therapeutics Committee, as required under state regulation.
- This is not a prior authorization issue; the issue is the plan should not dictate which brands of drugs hospitals are required to stock and administer.
- There are significant patient safety concerns. A requirement to have a specific biosimilar available based on the patient's health plan would require significant resources to procure, store, label, and dispense the payer-specific biosimilar to the patient. There are currently 11 biosimilars approved in the U.S. with 188 more in development and 260 approved in some international markets. If this became the standard, the additional time involved to order, store, label and pick the right payer-specific drug would add complexity to these processes. This consequence would be a significant increase in the risk of harmful medication errors by adding more steps to the medication management processes.
- There are significant operational, financial, safety and revenue compliance (different billing codes for different products) implications if payers designate which biosimilar products hospitals should use. Since each biosimilar has a different code for billing, if there is a mix-up of drugs, and the payer-specific biosimilar is not the one that is given, the payer would deny the payment and the patient would be responsible for paying the full cost of the medication.
- In addition, most health systems belong to group purchasing organizations, so the health system decides what's on their formulary and the group purchasing organization decides on how to contract for the drugs.
- We've engaged the American Hospital Association (AHA) on this issue and they are researching as well. AHA will reach out to the National Association of Insurance Commissioners, Department of Labor.
- We've engaged the California Medical Association (CMA) on this issue and they've been very helpful, reported that they are not yet hearing from CMA members on this issue.

- We are considering engaging consumer advocates.

2018 Member Engagement: CHA Managed Care Committee, select clinicians identified by committees and government relations leads. Biosimilars tend to be used in the cancer space, so this policy has severe implications for our oncology centers. The UCs have also reached out on this, as has City of Hope. Rita has indicated that Stanford has concerns and would reach out to USC Keck. CHA Medication Safety Committee and a select group of oncology centers.

Health Plan Engagement: Aetna

On Nov. 13, 2018, CHA met with Delia D. Johnson, Director of Compliance, California Market, Aetna and her team to discuss member concerns regarding Aetna's policy, including the lack of clarity regarding precertification requirements for pharmaceuticals being focused on the outpatient care setting. Aetna indicated it had not received similar feedback prior to our call. Aetna was unwilling to rescind its policy.

Stakeholder Engagement:

- State Regulatory Agencies
    - **California Department of Managed Health Care (DMHC) –** On Dec. 19, 2018, met with DMHC to discuss the policy. Included Cedars on the call (Deborah, Doug, Rita). DMHC shared that they would work with Aetna to better understand the policy. DMHC agreed that the policy is confusing but thinks this is largely a contracting issue. The best DMHC thought they could do is get the policy implementation delayed and have Aetna place more clear parameters around the policy (i.e. clarify that this only applies in the outpatient settings, that continuity of care provisions apply). The Knox-Keene Act already requires health plans to provide coverage for medically necessary prescription drugs, including non-formulary drugs determined to be medically necessary.

      On Jan. 11, DMHC confirmed that Aetna would be issuing a clarification to the policy in their monthly "Office Notes" publication to reflect that the prior authorization requirement for G-CSF products applies to outpatient services. If the patient has started a course of treatment while inpatient, providers should note this in the precertification request so Aetna can apply their continuity of care policies. Aetna confirmed this on Jan. 11 as well.

      The clarification was included in the March 2019 Provider Newsletter, available at https://www.aetna.com/health-care-professionals/newsletters-news/office-link-updates/state-specific-ca-march-2019/clarification-g-csf-products.html.

      CHA shared the clarification with Cedars and other members they are still very much concerned about patient safety and operational implications.

- Federal Regulatory Agencies

- N/A

- Provider Associations
  - **American Hospital Association (AHA) –** On Dec. 19, 2018, CHA met with AHA (included Cedars on the call). AHA shared at that time that their initial thinking was that the greatest lever on the issue would be at the state-level.

    We met with AHA again on March 27, and included Cedars, UC Health and UCLA Health. We discussed the importance of members sharing any examples of the policy adversely impacting patients/causing medication errors.

  - **California Medical Association (CMA)** – On Dec. 4, shared policy with Yvonne Choong, Vice President for the Center for Health Policy, who indicated they will check with their docs to see if they've raised any concerns regarding the policy. On Dec. 17, met with Catrina Reyes, Associate Director, Center for Health Policy, CMA, who indicated CMA shared the policy with their doctors and they expressed no concerns.

  - **Blue Shield of California (Blue Shield) –** In January, Carmela reached out Paul Markovich, President and CEO, Blue Shield of California, to better understand his perspective. On Jan. 10, Paul responded that his team was still looking into the specifics of the Aetna policy on biosimilars. Paul indicated that separate and apart from that, Blue Shield believes it is critical to pave the way for expanded use of biosimilars and is concerned about inappropriate attempts by pharma/biotech to stifle competition. Paul indicated he is not sure if Aetna is approaching this worthy goal in a way that Blue Shield would like to follow but it is worth noting this is an important goal. Paul also shared the following Washington Post article on some of the tactic to which he is referring: *Drugmakers' alleged scare tactics may hold back competition*.
- February 2019
- As a follow-up to a discussion CHA had with DMHC, DMHC worked with Aetna to better understand the policy. DMHC agreed that the policy is confusing but took the position that this is largely a contracting issue. The best DMHC thought they may be able to do is get the policy implementation delayed and have Aetna place more clear parameters around the policy (i.e. clarify that this only applies in the outpatient settings, that continuity of care provisions apply). The Knox-Keene Act already requires health plans to provide coverage for medically necessary prescription drugs, including non-formulary drugs determined to be medically necessary.
- DMHC and Aetna let CHA know that as a follow-up to DMHC and Aetna's discussion, Aetna would be issuing a clarification to the policy in their monthly "Office Notes" publication to reflect that the prior authorization requirement for G-CSF products applies to outpatient services. If the patient has started a course of treatment while inpatient, providers should note this in the precertification request so Aetna can apply their continuity of care policies.
- CHA and Cedars met to discuss DMHC's determination on Aetna's biosimilar policy/Aetna's revised biosimilar policy. Cedars expressed concern regarding DMHC's determination on Aetna's biosimilar policy/Aetna's revised biosimilar policy.
- CHA offered to convene another meeting between Cedars and DMHC to discuss Cedars' outstanding concerns. Cedars asked that CHA include additional impacted hospitals. CHA and Cedars agreed to do additional targeted outreach to members on this issue – beyond the UCs

(only others to yet express concern) – to see if others have additional outstanding concerns regarding Aetna's revised policy.
    - BJ reached out to a few members and hasn't heard that they have outstanding concerns regarding the policy.
- As DMHC has previously taken the position that they think this is largely a contracting issue, not confident DMHC would take any further action on the policy at this time, but we are willing to reconnect with them if members would like.
- As a reminder, AHA previously acknowledged that the greatest lever on this policy would likely be at the state level.

- March 2019- Conference call with AHA, CHA, Cedars and UC Oncology hospitals, discussed at April 3 Med Safety Meeting with more members concerned
- May 2019, Rita works with Senator Stone to draft a bill, ISMP Biosimilar Article
- July, 2019, Wall Street Article

Sept, 2019, Organizations Rita worked with directly who are addressing or in the process of addressing biosimilars and payer

- Vizient
- Ochsner
- University of Wisconsin
- Duke
- Hematology Oncology Pharmacy Association
- Yale New Haven
- City of Hope
- UCLA
- Oct 17,2019 CHA Med Safety Meeting Discussion
- Rita worked with several potential legislators, interested but unwilling to author the bill
- March 2020 Next Steps: This is an emerging issue that is important to our members. The CHA team should continue to monitor developments in this area, keeping in mind the federal and state Administrations' goals of decreasing the cost of medication, while balancing concerns that some of our members have shared regarding utilization management techniques that undermine the clinical judgement of providers, may put patients' health at unnecessary risk, and increase administrative burden of providers.

- **Review and develop new plan at CHA Medication Safety Committee Meeting**

Additional Resources:

- Congressional Research Services Report - *Biologics and Biosimilars: Background and Key Issues (Updated June 6, 2019)*: https://fas.org/sgp/crs/misc/R44620.pdf

- Amgen Biosimilars – *Biosimilars Update: 2019 Report (Sixth Edition):* https://www.amgenbiosimilars.com/pdfs/2019%20Trends%20in%20Biosimilars%20Report%20Electronic%20Version%20-%20USA-BIO-80182.pdf
- July 2019 Vizient Drug Price Forecast: https://www.vizientinc.com/Our-solutions/Pharmacy-Solutions/Drug-Price-Forecast-public
- Center for Biologics article - UnitedHealthcare Names 3 Biosimilars Preferred Treatments in 2019 MA Plans: https://www.centerforbiosimilars.com/news/unitedhealthcare-names-3-biosimilars-preferred-treatments-in-2019-ma-plans

Payer	Medication	Preferred Product	Policy
Aetna	Epogen®	Retacrit®	Epogen® or Procrit® require treatment failure (t/f) of Retacrit
	Neulasta®	Fulphila® or Udenyca®	Neulasta® and Ziextenzo® requires t/f of Fulphila® or Udenyca®
	Neupogen®	Nivestym® or Zarxio®	Neupogen® or Granix® requires t/f of Zarxio® and Nivestym®
	Remicade®	Remicade®	Inflectra® or Renflexis® requires t/f of all least cost brands (indication specific – includes Remicade®)
Anthem Blue Cross	Neupogen®	Zarxio®	Granix®, Neupogen®, or Nivestym® requires t/f of Zarxio® or Zarxio® is not FDA approved for the prescribed indication and the requested product is
	Remicade®	Remicade®	Inflectra®/Renflexis® requires t/f of Remicade® or individual has been receiving non-preferred product & has switched between infliximab products once
Blue Shield of Ca	Epogen®	Retacrit®	Epogen® or Procrit® requires t/f of Retacrit®
	Neulasta®	Neulasta® or Udenyca®	Fulphila® requires t/f of Neulasta® or Udenyca®
	Neupogen®	Zarxio®	Granix®, Neupogen®, or Nivestym® requires t/f of Zarxio®
Cigna	Neupogen®	Granix® or Zarxio®	Neupogen® or Nivestym® requires t/f of Granix® & Zarxio® or continuation to complete current cycle of chemo, or use in hematopoietic cell transplant
	Remicade®	Remicade®	Inflectra® or Renflexis® requires t/f of Remicade® (applies for employer group benefit plan and individual family plans)
UHC	Avastin®	Mvasi®	Avastin® or Zirabev® requires t/f of Mvasi®
	Epogen®	Retacrit®	Epogen® or Procrit® requires t/f of Retacrit®
	Herceptin®	Kanjinti®	Other trastuzumab products require t/f of Kanjinti®
	Neulasta®	Neulasta®	Fulphila® or Udenyca® require t/f of Neulasta®
	Neupogen®	Zarxio®	Granix®, Neupogen®, or Nivestym® requires t/f of Zarxio®
	Remicade®	Inflectra® or Remicade®	Avsola® or Renflexis® requires t/f of Inflectra® and Remicade®

- Highlighted drugs are for cancer patients
- Epogen is used in dialysis patients and those with anemia due to diseases
- Remicade is for Crohn's disease and ulcerative colitis
- Herceptin (5 biosimilars) and Avastin (2 biosimilars) biosimilars were approved later in 2019; therefore we anticipate this list to change soon

Payer Strategies and Implications

Shift Cancer and Infusions away from Health-Systems

- Loss of patients and revenue
- Patient safety risks

White Bagging

- Payer requires that patient specific drugs sent to providers vs purchasing the drug
- Significant safety and financial margin implications
- Conflicts with regulatory requirements, CMS Conditions of Participation

Biosimilars

- Payers are determining which biosimilars health-systems should use for patients
- Significant health-system financial and patient safety and out of pocket cost implications

Risk-based contracts may exclude high cost drugs resulting in White Bagging for health-system and non-licensed clinics

White Bagging

- Under white bagging, payers purchase the drugs through designated pharmacies, which then ships them to the provider for compounding and administration.
- Reduces revenue since unable to charge for medications
- Practice is in conflict with CMS Conditions of Participation
  - The hospital must have pharmaceutical services that meet the needs of the patients.... Interpretive Guidelines §482.25What is included in pharmaceutical services? Pharmaceutical services encompass the functions of procuring, storing, compounding, re-packaging, and dispensing all medications, biologicals, chemicals and medication-related devices within the hospital
- Potential product integrity issue since drugs not procured by pharmacy services
- Patient-specific drug supply creates safety risks and operational complexity
- Physician offices

  How is sterile compounding performed to prevent contamination and infections?

Biosimilar Product Information | FDA	Column1	Column2	Column3
Biosimilar Name	**Approval Date**	**Reference Product**	**Primary Use(s)**
Fulphila (pegfilgrastim-jmdb)	June 2018	Neluasta (pegfilgrastim)	Cancer
Udenyca (pegfilgrastim-cbqv)	November 2018	Neulasta (pegfilgrastim)	Cancer
Ziextenzo (pegfilgrastim-bmez)	November 2019	Neluasta (pegfilgrastim)	Cancer
Herzuma (trastuzumab-pkrb)	December 2018	Herceptin (trastuzumab)	Cancer
Kanjinti (trastuzumab-anns)	June 2019	Herceptin (trastuzumab)	Cancer
Ogivri (trastuzumab-dkst)	December 2017	Herceptin (trastuzumab)	Cancer
Ontruzant (trastuzumab-dttb)	January 2019	Herceptin (trastuzumab)	Cancer
Trazimera (trastuzumab-qyyp)	March 2019	Herceptin (trastuzumab)	Cancer
Zirabev (bevacizumab-bvzr)	June 2019	Avastin (bevacizumab)	Cancer
Mvasi (Bevacizumab-awwb)	September 2017	Avastin (bevacizumab)	Cancer
Nivestym (filgrastim-aafi)	July 2018	Neupogen (filgrastim)	Cancer
Zarxio (Filgrastim-sndz)	March 2015	Neupogen (filgrastim)	Cancer
Ruxience (rituximab-pvvr)	July 2019	Rituxan (rituximab)	Cancer and other immune disorders
Truxima (rituximab-abbs)	November 2018	Rituxan (rituximab)	Cancer and other immune disorders
Avsola (infliximab-axxq)	December 2019	Remicade (infliximab)	Inflammatory Bowel Disease
Inflectra (Infliximab-dyyb)	April 2016	Remicade (infliximab)	Inflammatory Bowel Disease
Ixifi (infliximab-qbtx)	December 2017	Remicade (infliximab)	Inflammatory Bowel Disease
Renflexis (Infliximab-abda)	May 2017	Remicade (infliximab)	Inflammatory Bowel Disease
Abrilada (adalimumab-afzb)	November 2019	Humira (adalimumab)	Inflammatory Bowel Disease, Rheumatoid Arthritis
Amjevita (Adalimumab -atto)	September 2016	Humira (adalimumab)	Inflammatory Bowel Disease, Rheumatoid
Cyltezo (Adalimumab-adbm)	August 2017	Humira (adalimumab)	Arthritis
Hadlima (adalimumab-bwwd)	July 2019	Humira (adalimumab)	Inflammatory Bowel Disease, Rheumatoid
Hyrimoz (adalimumab-adaz)	October 2018	Humira (adalimumab)	Inflammatory Bowel Disease, Rheumatoid Arthritis
Retacrit (epoetin alfa-epbx)	May 2018	Epogen (epoetin-alfa)	Kidney failure, cancer, other chronic diseases
Erelzi (Etanercept-szzs)	August 2016	Enbrel (etanercept)	Rheumatoid arthritis
Eticovo (etanercept-ykro)	April 2019	Enbrel (etanercept)	Rheumatoid arthritis

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: March 4, 2020

TO: Medication Safety Committee Members

FROM: Doug O'Brien, PharmD, Regional Director for Inpatient Pharmacy Services, Kaiser Foundation Hospitals

SUBJECT: California's Carve Out of Pharmacy Benefits

SUMMARY

In November it was announced that there will be a carve out of the pharmacy benefit for Medi-Cal beneficiaries from managed-care plans and transitioning them to fee for service programs which implies moving 23 million Medi-Cal beneficiaries to a new pharmacy program by January 2021. DHCS cites this will standardize the Medi-Cal pharmacy benefits statewide, improve access to pharmacy services with a pharmacy network that included approximately 97% of the state's pharmacies, and strengthen California's ability to negotiate state supplemental drug rebates with drug manufacturers. Under the fee for service program, DHCS will directly reimburse pharmacies at their actual cost of acquiring prescription drugs. Beneficiaries will no longer be dependent on the pharmacy network of the managed care plan and will be able to obtain prescription drugs at almost all pharmacies in California.

The transition, however, changes local coordination activity to a statewide standardization, that may threaten they unique needs of local beneficiaries and pose serious health risks.

DISCUSSION

1. What does this change mean to your hospital pharmacy practices?
2. Are there issues that CHA needs to address with DHCS?

Attachments: California Carving Out Pharmacy Benefits and Going FFS

BJB:br

California Carving Out Pharmacy Benefits and Going FFS

- Keith Loria

November 18, 2019

- News, Healthcare Policy

The State of California, under a directive from Governor Gavin Newsom, is "carving out" the pharmacy benefit for Medi-Cal beneficiaries from managed-care plans and transitioning to a fee-for-service (FFS) program, moving 13 million Medi-Cal beneficiaries to a new pharmacy program by January 2021.

The California Department of Health Care Services (DHCS) cites that transitioning pharmacy services from managed care to FFS will standardize the Medi-Cal pharmacy benefit statewide; improve access to pharmacy services with a pharmacy network that includes approximately 97% of the state's pharmacies; and strengthen California's ability to negotiate state supplemental drug rebates with drug manufacturers.

In November, DHCS awarded a five-year contract to a subsidiary of Magellan Health to manage its pharmacy benefit services statewide, effective Jan. 1, 2021.

Perry Cohen, CEO of consulting service The Pharmacy Group, recently was at the California Association of Health Plans (CAHP) meeting where he was on a panel to address this issue and says the switch to Magellan all at once will be problematic.

"It's the wrong way to implement it," he says. "It's going to be very disruptive to members and their level of service. For instance, there will be two 800-numbers to call—one for health plans and a second for pharmacy—and they're going to get confused."

What it all means

Under managed-care plans, DHCS, which administers Medi-Cal, pays managed care plans capitated payments, a portion of which cover the costs of prescription drugs. These payments are determined by the negotiated prices between the managed care plans and the pharmacies. Medi-cal beneficiaries can only obtain prescription drugs within their managed care plans' pharmacy network.

Anh Nguyen, assistant professor of economics at Carnegie Mellon University's Tepper School of Business, explains under the fee-for-service program, DHCS will directly reimburse pharmacies at their actual cost of acquiring prescription drugs (plus other predetermined fees). Additionally, Medi-cal beneficiaries will no longer be dependent on the pharmacy network of the managed care plan and can obtain prescription drugs to almost all pharmacies in California.

Jarrod McNaughton, CEO at Inland Empire Health Plan, headquartered in Rancho Cucamonga, California, notes when the state created Medi-Cal Managed Care Plans, its desire was to fashion a system of care that coordinated benefits for members, providing access to quality providers in a cost-effective manner. The emphasis was on preventive and primary care for the now nearly 11 million Medi-Cal beneficiaries in the state.

“This new direction in Medi-Cal is taking out of the plan responsibility for one of the key elements of care, the pharmacy benefit, and moving its function and operation to the state under a centralized pharmacy benefit manager (PBM),” he says. “What is currently a crucial cornerstone in coordinating care by making sure our members and providers have access to local plan team members to call and ask questions regarding the pharmacy benefit will be moved to a centralized function in Sacramento.”

The activities covered by the new program include claims processing for all outpatient drugs; pharmacy network administration; pharmacy drug rebate administration (both federal and state); prior authorization transactions; drug utilization review; customer service; and health plan coordination activities.

Implications on Medicaid plans

As proposed, McNaughton says local interventions that help ensure members receive their medication when they need it, avoid harmful drug interactions, monitor opioid prescriptions to avoid misuse and overprescribing, and ensure patients are utilizing their medications as prescribed will no longer be managed locally.

“Instead, these responsibilities will be outsourced to a private, for-profit PBM that would be hard-pressed to manage the unique needs and challenges of the Medi-Cal members who reside throughout the Inland Empire region,” he says. “Any delay or denial in access to needed medication will pose serious health risks and pressure on local hospital emergency rooms.”

Pharmacy Bills 2-26-20

AB 149 **(Cooper D) Controlled substances: prescriptions.**
Current Text: Chaptered: 3/11/2019 html pdf
Introduced: 12/14/2018
Last Amend: 2/19/2019
Status: 3/11/2019-Approved by the Governor. Chaptered by Secretary of State - Chapter 4, Statutes of 2019.
Location: 3/11/2019-A. CHAPTERED
Summary: Current law classifies certain controlled substances into designated schedules. Current law requires prescription forms for controlled substance prescriptions to be obtained from security printers approved by the department, as specified. Current law requires those prescription forms to be printed with specified features, including a uniquely serialized number. This bill would delay the requirement for those prescription forms to include a uniquely serialized number until a date determined by the Department of Justice that is no later than January 1, 2020. The bill would require, among other things, the serialized number to be utilizable as a barcode that may be scanned by dispensers.

AB 387 **(Gabriel D) Task force: adverse drug events: prescriptions.**
Current Text: Amended: 8/12/2019 html pdf
Introduced: 2/5/2019
Last Amend: 8/12/2019
Status: 8/30/2019-Failed Deadline pursuant to Rule 61(a)(12). (Last location was APPR. SUSPENSE FILE on 8/19/2019)(May be acted upon Jan 2020)
Location: 8/30/2019-S. 2 YEAR
Summary: Would create the Prescription Labeling and Adverse Drug Event Prevention Advisory Task Force, with membership as prescribed, to develop information, make recommendations, and report findings to the California State Board of Pharmacy, the Medical Board of California, and the Legislature on matters relating to the inclusion of the condition or purpose for which a drug is prescribed on prescription labels and adverse drug events.

AB 528 **(Low D) Controlled substances: CURES database.**
Current Text: Chaptered: 10/9/2019 html pdf
Introduced: 2/13/2019
Last Amend: 9/6/2019
Status: 10/9/2019-Approved by the Governor. Chaptered by Secretary of State - Chapter 677, Statutes of 2019.
Location: 10/9/2019-A. CHAPTERED
Summary: Would, on and after January 1, 2021, require a dispensing pharmacy, clinic, or other dispenser to instead report the information required by the CURES database no more than one working day after a controlled substance is released to a patient or a patient's representative, except as specified. The bill would similarly require the dispensing of a controlled substance included on Schedule V to be reported to the department using the CURES database. The bill would make conforming changes to related provisions.

AB 690 **(Aguiar-Curry D) Pharmacies: relocation: remote dispensing site pharmacy: pharmacy technician: qualifications.**
Current Text: Chaptered: 10/9/2019 html pdf
Introduced: 2/15/2019
Last Amend: 7/1/2019
Status: 10/9/2019-Approved by the Governor. Chaptered by Secretary of State - Chapter 679, Statutes of 2019.
Location: 10/9/2019-A. CHAPTERED
Summary: Would authorize relocation of a pharmacy that is destroyed or severely damaged as a result of a natural disaster or due to events that led to a declared federal, state, or local emergency, if no changes are made to the management and control, or ownership, of the pharmacy, and all applicable laws and regulations are followed, and require that the board be notified of the relocation immediately upon identification of the new location. The bill would specify the qualifications for a registered pharmacy technician to work at a remote dispensing site pharmacy, relating to licensing, certification, education, and minimum work experience, including completion of at least 2,000 hours of experience within the previous 2 years.

AB 714 **(Wood D) Opioid prescription drugs: prescribers.**
Current Text: Chaptered: 9/5/2019 html pdf
Introduced: 2/19/2019
Last Amend: 6/17/2019
Status: 9/5/2019-Approved by the Governor. Chaptered by Secretary of State - Chapter 231, Statutes

of 2019.
Location: 9/5/2019-A. CHAPTERED
Summary: Current law requires a prescriber, as defined, to offer to a patient a prescription for naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid depression when certain conditions are present, including if the patient presents with an increased risk for overdose or a history of substance use disorder, and to provide education on overdose prevention to patients receiving a prescription and specified other persons. This bill would make those provisions applicable only to a patient receiving a prescription for an opioid or benzodiazepine medication, and would make the provisions specific to opioid-induced respiratory depression, opioid overdose, opioid use disorder, and opioid overdose prevention, as specified. The bill, among other exclusions, would exclude from the above-specified provisions requiring prescribers to offer a prescription and provide education prescribers when ordering medications to be administered to a patient in an inpatient or outpatient setting.

AB 824 **(Wood D) Business: preserving access to affordable drugs.**
Current Text: Chaptered: 10/7/2019 html pdf
Introduced: 2/20/2019
Last Amend: 9/4/2019
Status: 10/7/2019-Approved by the Governor. Chaptered by Secretary of State - Chapter 531, Statutes of 2019.
Location: 10/7/2019-A. CHAPTERED
Summary: Would provide that an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, is to be presumed to have anticompetitive effects if a nonreference drug filer receives anything of value, as defined, from another company asserting patent infringement and if the nonreference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the nonreference drug filer's product for any period of time, as specified. The bill would provide various exceptions to this prohibition, including, among others, if the agreement has directly generated procompetitive benefits and the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement. The bill would make a violation of these provisions punishable by a civil penalty that is recoverable only in a civil action brought by the Attorney General, as specified. The bill would provide that a violator is liable for any other remedies available under the Cartwright Act, the Unfair Practices Act, or the unfair competition law. The bill would require a cause of action to enforce those provisions be commenced within 4 years after the course of action accrued. The bill would define various terms for these purposes.

AB 973 **(Irwin D) Pharmacies: compounding.**
Current Text: Chaptered: 8/30/2019 html pdf
Introduced: 2/21/2019
Last Amend: 5/13/2019
Status: 8/30/2019-Approved by the Governor. Chaptered by Secretary of State - Chapter 184, Statutes of 2019.
Location: 8/30/2019-A. CHAPTERED
Summary: Would require the compounding of drug preparations by a pharmacy for furnishing, distribution, or use to be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The bill, by imposing a new requirement on pharmacies, the violation of which would be a crime, would impose a state-mandated local program. The bill would authorize the board to adopt regulations to impose additional standards for compounding drug preparations.

AB 1803 **(Committee on Health) Pharmacy: health care coverage: claims for prescription drugs sold for retail price.**
Current Text: Chaptered: 7/12/2019 html pdf
Introduced: 2/28/2019
Status: 7/12/2019-Approved by the Governor. Chaptered by Secretary of State - Chapter 114, Statutes of 2019.
Location: 7/12/2019-A. CHAPTERED
Summary: The Pharmacy Law requires a pharmacy to inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, except as specified, and, if the customer pays the retail price, requires the pharmacy to submit the claim to the customer's health care service plan or health insurer. This bill would instead make the provision requiring the pharmacy to submit the claim to the health care service plan or health insurer operative on January 1, 2020. The bill would also repeal a provision that is similar to the provision being amended by the bill.

AB 2077 **(Ting D) Hypodermic needles and syringes.**
Current Text: Introduced: 2/5/2020 html pdf
Introduced: 2/5/2020

Status: 2/6/2020-From printer. May be heard in committee March 7.
Location: 2/5/2020-A. PRINT
Summary: Current law prohibits, except as specified, the sale of a hypodermic needle or syringe at retail except upon the proscription of a physician, dentist, veterinarian, podiatrist, or naturopathic doctor.This bill would repeal that provision.

AB 2100 **(Wood D) Medi-Cal: pharmacy benefits.**
Current Text: Introduced: 2/5/2020 html pdf
Introduced: 2/5/2020
Status: 2/20/2020-Referred to Com. on HEALTH.
Location: 2/20/2020-A. HEALTH
Summary: By executive order, the Governor directed the State Department of Health Care Services to transition pharmacy services for Medi-Cal managed care to a fee-for-service benefit by January 1, 2021. Current law requires the department to convene an advisory group to receive feedback on the changes, modifications, and operational timeframes on the implementation of pharmacy benefits offered in the Medi-Cal program, and to provide regular updates on the pharmacy transition, including a description of changes in the division of responsibilities between the department and managed care plans relating to the transition of the outpatient pharmacy benefit to fee-for-service. This bill would require the department to establish the Independent Medical Review System (system) for the outpatient pharmacy benefit, and to develop a framework for the system that models the above-described requirements of the Knox-Keene Health Care Service Plan Act.

AB 2288 **(Low D) Schedule II controlled substances: partial fill.**
Current Text: Introduced: 2/14/2020 html pdf
Introduced: 2/14/2020
Status: 2/15/2020-From printer. May be heard in committee March 16.
Location: 2/14/2020-A. PRINT
Summary: The Pharmacy Law specifies the functions pharmacists are authorized to perform, including to administer, orally or topically, drugs and biologicals pursuant to a prescriber's order, and to administer immunizations pursuant to a protocol with a prescriber. Current law authorizes a pharmacist to dispense a Schedule II controlled substance as a partial fill if requested by the patient or prescriber. A violation of the Pharmacy Law is a crime. This bill would require a pharmacist to offer, to a patient, to dispense a Schedule II controlled substance containing an opioid as a partial fill if the prescription is for greater than 7 days. By expanding the scope of a crime, the bill would impose a state-mandated local program.

AB 2983 **(Holden D) Pharmacy provider: billing.**
Current Text: Introduced: 2/21/2020 html pdf
Introduced: 2/21/2020
Status: 2/21/2020-Introduced. To print.
Location: 2/21/2020-A. PRINT
Summary: Would prohibit pharmacy providers from billing the Medi-Cal program for any prescribed drug that has been automatically filled, regardless of whether that prescribed drug has been dispensed by mail order or retail.

ACR 105 **(Chiu D) Prescription drug prices.**
Current Text: Introduced: 6/17/2019 html pdf
Introduced: 6/17/2019
Status: 8/28/2019-Re-referred to Com. on HEALTH.
Location: 8/28/2019-S. HEALTH
Summary: This measure would state the Legislature's commitment to lower the cost of prescription drugs for all Californians and to support the expansion of California's single-purchaser system for prescription drugs, and would encourage the Governor to engage with the States of Washington and Oregon and others who wish to partner with our state to lower prescription drug prices across the nation.

SB 159 **(Wiener D) HIV: preexposure and postexposure prophylaxis.**
Current Text: Chaptered: 10/7/2019 html pdf
Introduced: 1/23/2019
Last Amend: 9/5/2019
Status: 10/7/2019-Approved by the Governor. Chaptered by Secretary of State. Chapter 532, Statutes of 2019.
Location: 10/7/2019-S. CHAPTERED
Summary: Would authorize a pharmacist to furnish preexposure prophylaxis and postexposure prophylaxis in specified amounts and would require a pharmacist to furnish those drugs if certain conditions are met, including that the pharmacist determines the patient meets the clinical criteria for preexposure prohylaxis or postexposure prophylaxis consistent with federal guidelines. The bill would

require a pharmacist, before furnishing preexposure prophylaxis or postexposure prophylaxis, to complete a training program approved by the board. Because a violation of these requirements would be a crime, this bill would impose a state-mandated local program.

SB 377 **(McGuire D) Juveniles: psychotropic medications: medical information.**
Current Text: Chaptered: 10/7/2019 html pdf
Introduced: 2/20/2019
Last Amend: 9/6/2019
Status: 10/7/2019-Approved by the Governor. Chaptered by Secretary of State. Chapter 547, Statutes of 2019.
Location: 10/7/2019-S. CHAPTERED
Summary: Current law requires the Medical Board of California to review specified data provided by the State Department of Health Care Services and the State Department of Social Services regarding Medi-Cal physicians and their prescribing patterns of psychotropic medications and related services for dependents and wards of the juvenile court in order to determine if any potential violations of law or excessive prescribing of psychotropic medications inconsistent with the standard of care exist and, if warranted, to conduct an investigation. This bill would require, by September 1, 2020, the forms developed by the Judicial Council to include a request for authorization by the child or the child's attorney to release the child's medical information to the Medical Board of California in order to ascertain whether there is excessive prescribing of psychotropic medication inconsistent with a specified standard of care.

SB 569 **(Stone R) Controlled substances: prescriptions: declared local, state, or federal emergency.**
Current Text: Chaptered: 10/9/2019 html pdf
Introduced: 2/22/2019
Last Amend: 7/2/2019
Status: 10/9/2019-Approved by the Governor. Chaptered by Secretary of State. Chapter 705, Statutes of 2019.
Location: 10/9/2019-S. CHAPTERED
Summary: Would authorize a pharmacist, during a declared local, state, or federal emergency pursuant to which the board issues a notice that the board is waiving the application of the provisions of the Pharmacy Law, to fill a prescription for a controlled substance for use by a patient who cannot access medications as a result of the declared local, state, or federal emergency, regardless of whether the prescription form meets the above-specified requirements, if certain other requirements are met, including that the prescription is written and dispensed within the first 2 weeks of the notice issued by the board. The bill would require the patient to demonstrate, to the satisfaction of the pharmacist, their inability to access medications. The bill would prohibit refills under these provisions and would limit the dispensing of a Schedule II controlled substance to a 7-day supply.

SB 650 **(Rubio D) Cancer Medication Advisory Committee.**
Current Text: Amended: 7/8/2019 html pdf
Introduced: 2/22/2019
Last Amend: 7/8/2019
Status: 8/30/2019-Failed Deadline pursuant to Rule 61(a)(12). (Last location was APPR. SUSPENSE FILE on 8/14/2019)(May be acted upon Jan 2020)
Location: 8/30/2019-A. 2 YEAR
Summary: Would require the California State Board of Pharmacy to establish the Cancer Medication Advisory Committee for the purpose of identifying the best mechanism to enable the transfer of unused cancer medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. The bill would require the committee to be composed of 9 specified members and would require members of the committee to serve without compensation.

SB 655 **(Roth D) Pharmacy.**
Current Text: Chaptered: 8/30/2019 html pdf
Introduced: 2/22/2019
Last Amend: 4/11/2019
Status: 8/30/2019-Approved by the Governor. Chaptered by Secretary of State. Chapter 213, Statutes of 2019.
Location: 8/30/2019-S. CHAPTERED
Summary: The Pharmacy Law provides for the licensing and regulation of pharmacists and pharmacies by the California State Board of Pharmacy in the Department of Consumer Affairs. That law authorizes a pharmacy technician trainee to be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacist. That law prohibits the externship from being for a period of more than 120 hours, except if a pharmacy technician trainee's externship involves the rotation between a community pharmacy and a hospital pharmacy, in which case the externship is authorized to be for a period of up to 320 hours. That law prohibits more than 120 hours of the 320 hours from being completed in a community pharmacy setting or in a single

department in a hospital pharmacy. This bill would instead require the externship to be for a period of no fewer than 120 hours and no more than 140 hours.

SB 852 **(Pan D) Health care: prescription drugs.**
Current Text: Introduced: 1/13/2020 html pdf
Introduced: 1/13/2020
Status: 1/22/2020-Referred to Com. on RLS.
Location: 1/13/2020-S. RLS.
Summary: Would state the intent of the Legislature to introduce legislation to require the State of California to manufacture generic prescription drugs for the purposes of controlling prescription drug costs. The bill would also make related findings and declarations.

SB 885 **(Pan D) Sexually transmitted diseases.**
Current Text: Introduced: 1/23/2020 html pdf
Introduced: 1/23/2020
Status: 2/6/2020-Referred to Coms. on B., P. & E.D., HEALTH, and JUD.
Location: 2/6/2020-S. B., P. & E.D.
Summary: Would specify that family planning services for which a Medi-Cal managed care plan may not restrict a beneficiary's choice of a qualified provider include sexually transmitted disease (STD) testing and treatment. The bill would, subject to an appropriation by the Legislature, authorize an office visit to a Family PACT waiver provider or Medi-Cal provider for STD-related services for uninsured, income-eligible patients, or patients with health care coverage who have confidentiality concerns and who are not at risk for pregnancy, to be reimbursed at the same rate as comprehensive clinical family planing services.

SB 966 **(Nielsen R) Worker status: independent contractors: pharmacists.**
Current Text: Introduced: 2/11/2020 html pdf
Introduced: 2/11/2020
Status: 2/20/2020-Referred to Com. on L., P.E. & R.
Location: 2/20/2020-S. L., P.E. & R.
Summary: Current law establishes that, for purposes of the Labor Code, the Unemployment Insurance Code, and the wage orders of the Industrial Welfare Commission, a person providing labor or services for remuneration is considered an employee rather than an independent contractor unless the hiring entity demonstrates that the person is free from the control and direction of the hiring entity in connection with the performance of the work, the person performs work that is outside the usual course of the hiring entity's business, and the person is customarily engaged in an independently established trade, occupation, or business. This test is commonly known as the "ABC" test. Current law exempts specified occupations and business relationships from the application of Dynamex and these provisions. Existing law instead provides that these exempt relationships are governed by the test adopted in S. G. Borello & Sons, Inc. v. Department of Industrial Relations (1989) 48 Cal.3d 341. This bill would expand the above-described exemptions to also include individuals who are licensed pharmacists.

SB 983 **(Rubio D) Unused medications: cancer medication recycling.**
Current Text: Introduced: 2/12/2020 html pdf
Introduced: 2/12/2020
Status: 2/20/2020-Referred to Coms. on B., P. & E.D. and JUD.
Location: 2/20/2020-S. B., P. & E.D.
Summary: Would establish a program for the collection and distribution of eligible unused cancer medications, to be known as the Cancer Medication Recycling Act. The bill would require each participating practitioner, as defined, in the collection and distribution of those medications to be registered with the board, as specified, and would require the board to create a registry for participating practitioners, including developing both a donor and a recipient form containing specified information. The bill would authorize the board to charge a fee, not to exceed $300, as specified, to issue or renew the registration certificate of a participating practitioner under the program. The fee would be deposited in the Contingent Fund of the Medical Board of California.

SB 1084 **(Umberg D) Pharmacy: dispensing: controlled substances.**
Current Text: Introduced: 2/19/2020 html pdf
Introduced: 2/19/2020
Status: 2/20/2020-From printer. May be acted upon on or after March 21.
Location: 2/19/2020-S. RLS.
Summary: Would, with certain exceptions require a pharmacist who dispenses in solid oral dosage form a controlled substance in Schedule II or Schedule IIN of the federal Controlled Substances Act to dispense it in a lockable vial, as defined, provide an educational pamphlet on controlled substances, and, if the lockable vial uses an alphanumeric or other code, include the code in any patient notes in the database or other system used by the pharmacy in the dispensing of prescription drugs.

Total Measures: 23
Total Tracking Forms: 23

Susan Fanelli
Acting Director

State of California—Health and Human Services Agency
California Department of Public Health

GAVIN NEWSOM
Governor

August 18, 2019

AFL 19-27

TO: General Acute Care Hospitals

SUBJECT: Notice of Stakeholder Meeting for General Acute Care Hospital Clinical Laboratory, Pharmaceutical, and Dietetic Services Regulations

All Facilities Letter (AFL) Summary

This AFL notifies facilities that the California Department of Public Health (CDPH), Center for Health Care Quality (CHCQ) is holding a stakeholder meeting on August 30, 2019, to discuss general acute care hospital (GACH) clinical laboratory, pharmaceutical, and dietetic services regulations.

CDPH is holding a stakeholder meeting to discuss updating the GACH clinical laboratory, pharmaceutical and dietetic services regulations. The meeting will be held at:

Date	August 30, 2019
Time	2:00 PM to 3:30 PM
Location	1500 Capitol Avenue Training Room C Sacramento, CA 95814

CDPH would like to discuss and hear your ideas for updating regulations for these GACH services. Please come to the meeting prepared to share your comments and suggestions after reviewing the “Questions for Stakeholder Engagement – Clinical Laboratory, Pharmaceutical, and Dietetic Services”.

There is limited seating, so if you are attending in-person, please reserve your seat by August 23, 2019, by emailing CHCQRegulationsUnit@cdph.ca.gov. If you are attending via WebEx, please register with the WebEx Registration link. When choosing an audio connection, select “I will call in.”

Please check the Regulation Stakeholder Meetings webpage for updates and opportunities to comment. If you have any questions about this AFL, please email CHCQRegulationsUnit@cdph.ca.gov.

Sincerely,

Original signed by Heidi W. Steinecker

Heidi W. Steinecker
Deputy Director

Attachments:
“Questions for Stakeholder Engagement – Clinical Laboratory, Pharmaceutical, and Dietetic Services” (PDF)
“Existing Title 22 Clinical Laboratory, Pharmaceutical, and Dietetic Service Regulations” (PDF)

Center for Health Care Quality, MS 0512 . P.O. Box 997377 . Sacramento, CA 95899-7377
(916) 324-6630 . (916) 324-4820 FAX
Department Website (cdph.ca.gov)

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LICENSING AND CERTIFICATION

Questions / Information for Stakeholder Engagement

GACH, Clinical Laboratory, Pharmaceutical, and Dietetic Services

To be held: August 30, 2019

Clinical Laboratory Service (§70241 - §70249)

The Department anticipates revising the GACH clinical laboratory service regulations to bring the language of the regulations up to current professional standards.

1. What legal and professional standards should the director of the clinical laboratory service be required to follow?
2. What are the minimum routine laboratory services that a clinical laboratory within a hospital should supply?
3. Do the current California Radiation Control regulations sufficiently address the use, storage, and disposal of all radioactive material by the clinical laboratory service?
4. What quality indicator data does the clinical laboratory service currently collect? How frequently does the lab review data as a part of a quality assessment and performance improvement program? Does this include adverse events.

For clinical laboratory services that depend on outside blood banks and transfusion suppliers:

1. What evaluation method does the clinical laboratory service use to determine whether the suppliers of critical materials, equipment, and services meets their service needs?
2. What would the drawbacks or benefits be from inviting, whenever possible, the director of the blood bank and transfusion service, or his or her representative, to participate in the evaluation and selection of suppliers before an agreement is finalized with an outside blood bank
3. Should the contractual agreement between the blood bank and transfusion service and the outside blood bank and transfusion supplier include a brief explanation of how those expectations will be met?

Pharmaceutical Service (§70261 - §70269)

The Department anticipates revising the GACH pharmaceutical service regulations to bring the language of the regulations up to current professional standards.

1. Under what circumstances would it be beneficial to allow practitioners to prescribe drugs in hospitals, and which practitioners?
2. Who conducts medical reconciliation for high-risk patients upon admission to the hospital?
3. What are the drawbacks or benefits that may result from requiring the person taking a verbal or telephone order for drugs to record the name of the person calling in the order for the prescriber (the caller) as well as their own name (the person inscribing the verbal or telephone order), and allowing the pharmaceutical service to accept electronic signatures?
4. What are the drawbacks or benefits that may result from requiring a retrospective review of any drugs administered pursuant to a standing order (without a patient-specific prescription), and requiring the medical necessity for administering drugs pursuant to a standing order be documented in the patient's medical record?
5. What are the drawbacks or benefits that may result from requiring drug storage temperature logs to be maintained and readily available for three years?
6. What would be the drawbacks and benefits of requiring hospitals licensed pursuant to section 4029 of the Business and Professions Code to provide office space for the Director of the pharmaceutical service? What would be the drawbacks and benefits of requiring hospitals licensed pursuant to section 4029 of the Business and Professions Code that have pharmacy managers to provide office space for the pharmacy manager, while allowing offices to be shared if there are multiple pharmacy managers?

Dietetic Service (§70271 -70279)

The Department anticipates revising the GACH dietetic service regulations to bring the language of the regulations up to current professional standards.

1. What are the drawbacks or benefits that may result from requiring the refrigerator and freezer temperature reading logs be kept for 90 days
2. What are the drawbacks or benefits that may result from requiring cleaning and sanitizing of dishware to meet current standards regarding pre-cleaning and proper sanitizing?
3. Should a nutritional assessment that includes height, weight, and pertinent laboratory tests be completed upon admission?
4. Do hospitals have written policies and procedures for medical nutrition therapy that are reviewed at least annually?
5. Do hospital diet manuals presently include the purpose and principles of each diet, the meal pattern, the foods allowed and not allowed, and the nutritional adequacy and inadequacy for each type of diet provided? How frequently should a hospital diet manual be updated
6. What are the drawbacks or benefits that may result from requiring a patient's transfer discharge record to include a discharge summary of nutritional care provided, all nutritional care notes, nutritional assessments, and the nutritional care plan?
7. What are the drawbacks or benefits that may result from requiring that, during emergencies where the dietary service cannot prepare meals in the usual manner or cannot obtain meals from their regular outside meal provider, or during a state or federally declared disaster, the dietary service must provide meals that mirror the nutritional adequacy of the menus?

8. What are appropriate guidelines for the safe preparation of formula, human breast milk, and admixtures?

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TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy (Board) is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, includ-ing those sent by mail, facsimile, or e−mail to the ad-dresses listed under Contact Person in this Notice, must be received by the Board at its office on March 23, 2020.

The Board does not intend to conduct a Regulation Hearing on the matter, unless requested. Any interested person may submit a written request for a public hearing no later than 15 days prior to the close of the written comment period.

The Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Section 4005 of the Business and Professions Code (B and P) to implement, interpret, and make spe-cific Sections 4081, 4105, and 4333 of the Business and Professions Code, the Board is proposing to amend Sec-tion 1707 of Article 2 of Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Board proposes to amend Section 1707 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of amending the Board's regulation specific to waiver requirements for the off−site storage of records.

Existing pharmacy law specifies that protection of the public is the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions and generally authorizes the Board to adopt and amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy. Additionally, existing law authorizes the Board to issue a license to a pharmacy.

Existing law specifies the record keeping requirements for the manufacture, sale, acquisition, receipt, shipment, and disposition of dangerous drugs or dangerous devices (B and P section 4081). Additionally, current law requires that records of acquisition and disposition of dangerous drugs or dangerous devices be stored in a readily retrievable form (B and P section 4105). Lastly, existing statute requires that pharmacies keep a record of any prescriptions filled on the licensed premises of the pharmacy and allows for the Board to grant a waiver of that requirement (B and P section 4333 (a) and (c)(1)).

Some pharmacies struggle to find space to store these paper records and still maintain a safe working environment for their employees. This proposal will allow the Board more discretion when approving a waiver and clarify that a waiver will allow storage of these records outside of the licensed area of the pharmacy.

ANTICIPATED BENEFITS OF PROPOSAL

This proposal will benefit a pharmacy that lacks sufficient space to store records within the licensed area of the pharmacy by allowing the records to be stored outside the licensed premises while maintaining public protection. Smaller pharmacies as well as high−volume pharmacies do not have the physical space on the licensed premises to store the amount of records required by licensing regulations. This proposal will help to create a safer work environment by allowing the Board discretion to grant a waiver of the storage requirement so that a pharmacy can avoid the fire hazard as well as the health and safety hazard of storing boxes of files in a pharmacy with inadequate space.

CONSISTENCY AND COMPATIBILITY WITH EXISTING STATE REGULATIONS

During the process of developing these regulations and amendments, the Board conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Sections 17500−17630 Require Reimbursement: None.

Business Impact:

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees. This includes the ability of California businesses to compete with businesses in other states.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None.

Effect on Small Business:

While the Board does not have nor does it maintain data to define if any of its licensees (pharmacies) are a "small business" as defined in Government Code section 11342.610, the Board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. The proposed regulation does not require the use of specific computer software.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS

Impact on Jobs/New Businesses:

The Board has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the

State of California because this regulation is related to the storage of records and not jobs.

Benefits of Regulation:

The Board has determined that this regulatory proposal will benefit worker safety because the proposed regulation will allow pharmacies to minimize health and safety hazards within the pharmacy by allowing the storage of records outside of the licensed area of the pharmacy.

CONSIDERATION OF ALTERNATIVES

The Board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulation, and any document incorporated by reference, and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy's website http://www.pharmacy.ca.gov.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:
Lori Martinez

Address:
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833

Phone Number:
(916) 518−3078

Fax Number:
(916) 574−8618

E−Mail Address:
Lori.Martinez@dca.ca.gov

The backup contact person is:

Name:
Debbie Damoth

Address:
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833

Phone Number:
(916) 518−3090

Fax Number:
(916) 574−8618

E−Mail Address:
Debbie.Damoth@dca.ca.gov

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: March 4, 2020

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: New Member

SUMMARY

Upon her retirement, Jeannette Hanni has recommended a replacement from Sutter Health, Leah Hatfield, PharmD, BCPS. Jeannette advises "She is one of our stellar regional clinical managers and has been in an acting Exec Dir role for the past 8 months or so. She is thrilled at the possibility of participating on the committee. She's one of our up and comers and I would highly recommend her for the group." Please see Leah's CV attached.

ACTION REQESTED

- Member recommendation.

Attachments: Leah Hatfield CV

BJB:br

Leah M. Hatfield, PharmD, BCPS

CONTACT INFORMATION

Home Address: 316 Rialto Court
El Dorado Hills, CA 95762
(678) 637-6537 mobile
leahmhatfield@gmail.com

Work Address: Sutter Health System Office
2700 Gateway Oaks, Suite 2200
Sacramento, CA 95833
(916) 887-7011 office
HatfieLM@sutterhealth.org

ACADEMIC QUALIFICATIONS

Board Certified Pharmacotherapy Specialist 2006-present
Board of Pharmaceutical Specialties

Post Graduate Residency, Critical Care, ASHP Accredited 2005-2006
Naval Medical Center, San Diego, CA

Doctor of Pharmacy, *Magna cum laude*
Mercer University Southern School of Pharmacy 1998-2004
Atlanta, GA

PROFESSIONAL EXPERIENCE

Executive Director of Pharmacy Services, Interim March 2019- present
Area Clinical Pharmacy Manager Sept 2018- present
PGY1 Residency Program Director
Sutter Health, Sacramento, CA

- Provide senior strategic, operational, and clinical oversight for all pharmacy operations and programs in the 10-hospital Sutter Health Valley Operating Unit
- Direct responsibility for area-wide performance optimization and metrics, including: pharmacy operations, formulary management, medication quality and safety programs, and financial management for a 170M drug budget across the continuum of care.
- Collaborate with Area Executive Pharmacy Directors, senior hospital affiliate, and Sutter System Enterprise leadership to lead the design, implementation, alignment and support of all clinical, quality, and regulatory activities for 26 Sutter hospital affiliates.
- Collaborates with medical and organizational leadership to ensure the effective implementation of pharmacy initiatives. Oversees 5 direct FTEs and 45 indirect FTEs and is responsible for the development, marketing, coordination, and evaluation of specific clinical pharmacy programs.
- Lead the selection, hire management, mentoring, training, and succession planning for directors of pharmacy, clinical managers, clinical pharmacists, and pharmacy residents in the Valley Area.
- Evaluate and lead strategy in new opportunities to advance clinical and operational pharmacy programs that improve quality of care, patient safety, and responsibly manage costs. (i.e. pharmacy retail strategy, specialty pharmacy, automation and technology, supply chain, and clinical practice model innovations).
- Assist facility-specific leadership in development and review of all clinical pharmacy analytics,

policies, protocols, EHR order sets, educational materials, training programs, formulary review, and clinical trials operations to improve patient care.
- Serves as Residency Program Director for PGY1 Pharmacy Residency Program at Sutter Medical Center Sacramento

Clinical Pharmacy Team Leader, Acute Care and Emergency Services Jan 2017- July 2018
UNC Healthcare, Chapel Hill, NC

- Act as a leadership extension of the Assistant Director of Acute and Ambulatory Care Clinical Services to facilitate all leadership activities for 42 clinical pharmacist FTE's
- Independently address, mediate, and resolve issues within the area, including: workplace disagreements, mentor and coach pharmacists on service enhancement, corrective action process
- Facilitate meetings with clinical teams and contribute to Department of Pharmacy administrator-level meetings as the voice of acute care pharmacists
- Lead departmental clinical initiatives as the acute care pharmacist representative, including: formulary, transitions of care, Epic governance, drug shortages, disaster preparedness
- Facilitate global clinical responsibilities for acute care staff, including: Epic optimization, policy review, clinical guideline and order set development, quality improvement initiatives
- Ensure active engagement by acute care pharmacists to achieve Department of Pharmacy, UNC Medical Center, and UNC Healthcare goals, including: discharge prescription capture, transitions of care, and antimicrobial stewardship
- Manage the schedule and bi-weekly timecards for Acute Care Clinical Pharmacists
- Facilitate all Human Resources management tasks, including: professional development plans, annual evaluations, candidate recruitment and interviews, orientation and onboarding of new employees

Lead Clinical Pharmacist Specialist, Emergency Medicine June 2014- July 2018
UNC Medical Center, Chapel Hill, NC

- Manage all clinical and operational aspects of pharmacy services for a 93 bed Emergency Department, 30 bed observation unit, and accredited Level I adult and pediatric trauma center, TJC accredited Comprehensive Stroke and Chest Pain Center, seeing over 85,000 patients annually
- Coordinate all academic and professional development activities for 39 pharmacy residents in the largest pharmacy residency program in the US
- Educate and precept over 15 pharmacy student and resident learners annually and provide routine teaching lectures in Emergency Medicine Conference at UNC
- Design and implement >50 clinical and operational pathways and corresponding CPOE order sets for ten UNC Healthcare system emergency departments
- Provide clinical pharmacy consultation, education, and protocol review for Carolina Air Care and Orange County EMS pre-hospital personnel
- Develop and facilitate routine team-based multidisciplinary simulation events for common emergency scenarios for UNC Department of Emergency Medicine
- Provide bedside clinical services for all medical codes, code stroke, code STEMI, trauma, and behavioral health crisis events
- Serve as Chairman of the UNCMC Pharmacy Preceptor Development Committee, with responsibility for over 80 pharmacist preceptors
- Appointed to System ED Leadership Roundtable, System Disaster Preparedness Committee, Pharmacy and Therapeutics Committee, Pharmacy Practice Council

Interim Clinical Pharmacy Manager, Pediatric and Emergency Services April 2012-June 2014
Residency Program Director, PGY2 Pediatrics
UNC Healthcare, Chapel Hill, NC

- Served as the supervisor for 12 Pediatric Clinical Specialists, overseeing all operational activities within the pediatric pharmacy satellite to provide daily support to the 154 bed North Carolina Children's Hospital
- Restructured satellite operations, schedule, and clinical service distribution to optimize workload and efficiency and free two pharmacist FTE's for future expansion of clinical services into pediatric oncology and cystic fibrosis clinics
- Developed and implemented use of standard concentrations and exact volume preparations for all pediatric admixtures to enhance compliance with TJC and ISMP
- Designed and executed development of a comprehensive clinical and operational pharmacy service line in emergency medicine and obtained approval for dedicated FTEs
- Served as an Epic SuperUser and EPIC Validation team member, reviewed and developed a comprehensive pediatric medication build and all clinical order sets for neonatal and pediatric intensive care and emergency medicine
- Project manager for TJC Accreditation site visit, Pediatric Level I Trauma Center Accreditation , Epic system go-live, and ASHP Residency Accreditation evaluation
- Managed all aspects of clinical pharmacy services for a 60 bed Neonatal Critical Care Center and 30 bed Pediatric Intensive Care Unit
- Served on Student and Resident Advisory Council, Layered Learning Practice Model Steering Committee, Pharmacy Practice Council, Residency Progression Committee, One Pharmacy Community Practice Model Committee, Emergency Department Clinical Operations Group, and Medication Safety Committee
- Designed and implemented all pediatric, neonatal, and emergency medicine drug libraries for the Baxter Sigma Spectrum infusion pump implementation project

Clinical Pharmacist Specialist PRN, Emergency Medicine Jan 2008- April 2012
Grady Health System, Atlanta, GA

- Managed all aspects of pharmacy services for a 120 bed emergency department in a Level I Trauma Center, treating over 120,000 patients annually
- Provided bedside clinical services for all medical codes, stroke codes, and trauma events including all medication preparation and administration
- Served as an Emergency Medicine experiential preceptor for students, PGY1, and Critical Care and Emergency Medicine PGY2 residents
- Served as an Epic Subject Matter Expert in Emergency Medicine and Pediatrics, developed multiple clinical protocols and pathways, including: Rapid Sequence Intubation, Traumatic Brain Injury, Outpatient DVT/PE Management, and Stroke
- Afforded clinical administrative oversight for the Neonatal Intensive Care and Pediatric Burn Intensive Care services including: clinical protocols, medication safety policies, conversion to CPOE, guardrails for Alaris pumps, and staff development programs
- Fulfilled multiple administrative projects including: Joint Commission tracers, medication safety analyses, medication use evaluations, clinical intervention analyses, and staff development needs assessments
- Developed and conducted all pediatric training for GHS pharmacy staff and residents
- Served as Interim Director of Pharmacy Education from May 2008- September 2009, coordinating over 200 student advanced practice experiences for three schools of pharmacy and over 25 continuing education programs and competencies for staff

Clinical Pharmacist Specialist, Emergency Medicine Aug 2007- April 2011
Children's Healthcare of Atlanta at Egleston, Atlanta, GA

- Established and managed all aspects of a new clinical pharmacy service for a 40 bed Emergency Department and Trauma Center, treating over 60,000 patients annually
- Provided bedside clinical services for all medical emergencies, medical codes, intubations, and trauma events
- Designed and executed a new competency training program for all CHOA pharmacists to address Code Blue response, trauma care, disaster management, rapid sequence intubation, and management of common medical emergencies
- Conducted over 50 staff in-services and live Code Blue and trauma training for all pharmacists in the CHOA system
- Designed and delivered all pharmacotherapy instruction for the biannual Georgia Pediatric and Adult Trauma Specialist certification course
- Redesigned the residency interview process and performance standards for CHOA's PGY1 Pharmacy Residency as a member of the Residency Advisory Committee
- Served as the Student Coordinator and School of Pharmacy Liaison, coordinating and integrating 60 student rotations annually
- Served as an Emergency Medicine Preceptor for pharmacy students, CHOA PGY1 residents, and Grady PGY2 Emergency Medicine Residents

Visiting Clinical Assistant Professor of Pharmacy Practice July 2007- May 2008
Mercer University College of Pharmacy and Health Sciences
Clinical Pharmacist Specialist, Emergency Medicine, Grady Health System
Atlanta, GA

- Responsible for planning, coordinating, and teaching material in multiple didactic courses for both the Pharmacy and Physician Assistant programs.
- Didactic and experiential teaching in Critical Care and Emergency Medicine
- Maintained a clinical practice site and active employment in Emergency Medicine at Grady Health System and Children's Healthcare of Atlanta
- Coordinated, developed, and taught a new elective course in Pediatric Pharmacotherapy
- Designed the entire pharmacotherapy curriculum for the new Physician Assistant program in the College of Pharmacy and Health Sciences
- Served on the Admissions, Assessment, Continuing Education, Clinical Practice, and PA Curriculum committees
- Served on the Residency Advisory Committee at Children's Healthcare of Atlanta and Grady Health System

Lead Clinical Pharmacist Specialist, Critical Care June 2006- July 2007
Naval Medical Center, San Diego, CA

- Served as supervisor for 9 pharmacists and 13 technicians
- Attended daily multidisciplinary rounds, provided a total parenteral nutrition service, pharmacokinetic drug monitoring and dosing, drug information consults, multidisciplinary family care meetings, and Pediatric House Staff daily conferences
- Custom built a comprehensive clinical pharmacy program, providing services that had not previously existed at NMCSD
- First pharmacist to receive full order writing privileges under collaborative practice protocol with senior medical staff

- Served as the Student and Resident Education Coordinator, responsible for scheduling all clinical rotations in the facility and coordinating Residency Advisory Council activities
- Provided regular required pharmacology lectures and Grand Rounds presentations to medical interns and residents

Clinical Pharmacist Specialist, Active Duty Officer July 2004- July 2007
Naval Medical Center, San Diego, CA

- Assisted in operations of the Department of Defense's largest and busiest pharmacy department, dispensing 1.2 million prescriptions annually
- Served as Inpatient Clinical and Operations Supervisor from October 2004- July 2006, responsible for scheduling, oversight, and performance reviews for 18 inpatient pharmacists and 38 technicians
- Coordinated and supervised a pharmacist managed post-exposure prophylaxis and toxicology consult program for all military facilities in the San Diego area
- Served in medical readiness and humanitarian missions aboard the USS Nimitz, USS Reagan, USS Tarawa, and USNS Mercy, including three deployments
- Assisted Navy and Marine battle groups in managing pre-deployment medical clearance and safety evaluations, inventory planning, treatment algorithms, prescriptions, pharmacy operations, and global and tropical medicine preparedness
- Provided comprehensive clinical pharmacist services on the following services: NICU/PICU, Adult Medical/Surgical and Cardiac Intensive Care units, Emergency Medicine, and Internal Medicine Step-Down
- Served as Narcotics Supervisor from July 2006- July 2007, responsible for all controlled substance use, tracking, and safety throughout the hospital and ten surrounding branch clinic facilities
- Pharmacy representative on the hospital's Infection Control Committee, Code Blue Committee, NICU Advisory Group, Pediatrics Advisory Group, and Morale Welfare and Recreation Committee
- Provided pharmaceutical knowledge and expertise as a member of Joint Commission Root Cause Analysis teams and JAGMAN legal medical malpractice investigations

INVITED PROFESSIONAL PRESENTATIONS

Hatfield LM. *Seeing it Through: Recognizing Anxiety and Depression in Students and Residents and Promoting Self-Care and Resilience.* California Society of Health System Pharmacy Pacific Coast Preceptor Program, March 2019.

Hatfield LM, et al. *The Clinical Pharmacist's Role in Emergency Medicine*. Expert advisory panel presentation: American College of Emergency Physicians Scientific Assembly. October 2017.

Hatfield LM. *Stop the Bleeding: Updates in Anticoagulation Reversal*. ACPE Accredited CE Program, nationwide webinar: ASHP Pharmacy Grand Rounds, September 2016 and May 2017.

Hatfield LM, Willis TS. *Sepsis Programs: Resilience and Human Factors Associated with Implementation.* ACGME Accredited CE Program, Children's Hospital Association National Quality and Safety Conference, February 2016.

Hatfield LM. *Critical and Emergency Care: Traumatic Brain Injury, Toxicology, and Drug Dosing in ECMO.* Core Therapeutic Module and nationwide webinar for Board Certification Review, ASHP, 2015.

Hatfield, LM. *Let's Tox: Overview and Management of Common Ingestions and Exposures.* ACPE Accredited Nationwide Webinar: ASHP Pharmacy Grand Rounds, April 2014.

Hatfield, LM. *Heart to Heart: Recognizing Undiagnosed Congenital Heart Disease in the Emergency Department.* ACPE Accredited CE Program, ASHP Midyear Clinical Meeting, 2012.

Hatfield, LM. *Shot Through the Heart: Use of Intracardiac Epinephrine in Traumatic Arrest.* ACPE Accredited CE Program, ASHP Midyear Clinical Meeting, 2011.

Hatfield LM. *It's All About the Nose, Baby: Intranasal Sedation and Analgesia in the Emergency Department.* ACPE Accredited CE Program, ASHP Midyear Clinical Meeting, 2010.

Hatfield LM. *Essentials of Pharmacotherapy in Emergency Medicine.* ACGME/ENA Accredited CE Program: Georgia Trauma Specialist Course, 2010.

Hatfield LM. *Field Stabilization and Early Management of Traumatic Brain Injury and Penetrating Trauma*. ACGME/ENA Accredited CE Program: Georgia Trauma Specialist Course, 2010.

Hatfield LM, Rossetto JM. *When the Battlefield Comes to You: Pharmacotherapy in Domestic Mass Casualty Events*. ACPE Accredited CE Program, APhA Annual Meeting, 2007.

Phanco, LM. *Management of Adult and Pediatric Head Trauma in the Critical Care Setting.* ACPE Accredited Continuing Education: San Diego Society of Health System Pharmacists, 2006.

Phanco LM. *Impact of a Pharmacist Conducted Medication Reconciliation Program on Improving the Optimization of Patient Care.* ACPE Accredited CE Program: Western States Forum for Pharmacy Residents and Fellows, 2006.

Phanco LM. Wheeler KW. *The Clinical Pharmacist's Role as a Team Member in the Management of Chronic Kidney Disease.* ACPE Accredited Continuing Education Program: APhA Combined Forces Pharmacy Seminar, 2005.

Phanco LM. *APhA-ASP and You: Why Pharmacy Students Determine the Future of Our Profession. Presentation:* APhA Annual Meeting, guest visits to pharmacy schools, 2003.

GRANTS AND RESEARCH

Gehi A, Biese K, Deyo Z, **Hatfield L**, et al. *Optimizing Healthcare System Management of Emergency Department Patients with Atrial Fibrillation: A New Treatment Paradigm*
Bristol Myers Squibb Foundation, $1.9M grant

Quackenbush E, **Hatfield L**, et al. *A National, Hospital-Based, Sentinel Surveillance Study of the Clinical and Economic Impact of Bleeding and Bleeding Concerns due to the Use of Oral Anticoagulants (SOAR)*.
University of North Carolina IRB 16-1954

Quackenbush E, **Hatfield L**, et al. *Multicenter trial of Rivaroxaban for early discharge of pulmonary embolism from the Emergency Department (MERCURY PE)*.
University of North Carolina IRB 15-2982

Moll S, Myers J, **Hatfield L**, Jordan G. *Prospective, open- label study of andexanet alfa in patients receiving a factor Xa inhibitor who have acute major bleeding (ANNEXA-4).*
University of North Carolina IRB 15-0474

Hatfield L, Casciere B, Darby A, et al. *Emergency department venous thromboembolism management guideline: a pre and post implementation study*.
University of North Carolina IRB 15-0854

Hatfield L, Casciere B. *Clinical outcomes in patients treated with 4-factor prothrombin complex concentrates: a case series.*
University of North Carolina IRB 15-2828

PEER-REVIEWED PUBLICATIONS

Gehi AK, Deyo Z, **Hatfield L**, et al. Novel Care Pathway for Patients Presenting to the Emergency Department With Atrial Fibrillation. *Circ Cardiovasc Qual Outcomes*. 2018;11:e004129.

Goralski J, Young M, **Hatfield L**, et al. Old drugs for multi-drug resistant bugs: a novel colistin desensitization protocol in an allergic patient with cystic fibrosis. *Pharmacotherapy*. 2015; 83:28-32.

NON PEER-REVIEWED PUBLICATIONS

Hatfield LM, Shenvi CL**.** Just Tramadon't: The many reasons to avoid tramadol in the ED. *Emergency Physicians Monthly.* May 2019

Hatfield LM, Shenvi CL. Buprenorphine induction in the ED: the missing link in a broken system? *Emergency Physicians Monthly.* March 2019.

Hatfield LM, Shenvi CL. Could ketadex be the next ketofol? *Emergency Physicians Monthly.* November 2018.

Shenvi CL**, Hatfield LM.** Kratom: A legal drug of abuse. *Emergency Physicians Monthly*. October 2018.

Hatfield LM, Shenvi CL**.** Topical capsaicin for cannabinoid hyperemesis syndrome. *Emergency Physicians Monthly*. September 2018.

Hatfield LM, Doyle KS. Facts about DKA: An interview with an emergency medicine specialist. Feature patient education piece available at: **https://beyondtype1.org/facts-about-dka-an-interview-with-emergency-medicine-specialist/.** Beyond Type I. April 2018

Boise M, Burgos R, **Hatfield L.** Previously Healthy: a multi-media education campaign for pediatric diabetic ketoacidosis available at: **http://previouslyhealthy.org/.** Beyond Type I. April 2018.

Hatfield LM. Novel oral anticoagulant failure in VTE. *Emergency Physicians Monthly*. July 2017.

Hatfield LM. What is the risk of VTE on a long haul flight? *Emergency Physicians Monthly*. September 2016.

Mehrotra A, Buff TD, **Hatfield LM**, Kessler CS. Oral anticoagulation reversal. *Emergency Medicine Reports.* 2016;37:197-208.

Hatfield LM, Lesch CL, Koroby M. Special report: Implementation of KCentra for urgent warfarin reversal, practical considerations. *Pharmacy Practice News*. 2015; SR144:1-8.

PEER REVIEWED PROFESSIONAL POSTERS

D'Arcangelis J, Concha A, **Hatfield L**, et al. *Retrospective study of andexanet alfa vs. 4-factor prothrombin complex concentrate for reversal of factor Xa inhibitors in the setting of intracranial hemorrhage.* Poster presented at American Society of Health-System Pharmacists Midyear Meeting, December 2018.

Druga J, **Hatfield L**, Hatfield C, Pappas A, et al. *Implementation of an emergency department take-home medications process at a large, academic medical center.* Poster presented at American Society of Health-System Pharmacists Midyear Meeting, December 2017.

Tuttle H, Deyo Z, **Hatfield L**, Beek T, et al. *Optimizing the management of emergency department patients with atrial fibrillation.* Poster/ platform presented at Emergency Nursing Association Annual Conference, September 2017.

Beek T, **Hatfield L**, Ekker N, Abunada Y. *Implementation of a ketamine analgesia protocol to augment pain control in a large academic emergency department.* Poster/platform presented at University of North Carolina Health Care Nursing Quality and Research Conference, April 2017.

Deyo Z, **Hatfield L**, Chen, S. Mendys P, Tuttle H, Walker J, Gehi A, Biese K. *A Novel Care Pathway for Patients Presenting to the Emergency Department with Atrial Fibrillation Reduces Admission Rate and Hospital Length of Stay.* Poster presented at American Heart Association Annual Meeting, 2016

Hatfield L, Casciere B. *Clinical outcomes in patients treated with 4-factor prothrombin complex concentrates: a case series.* Poster presented at Society of Critical Care Medicine Annual Meeting, 2016

Hatfield L, Casciere B, Darby A, et al. *Emergency department venous thromboembolism management guideline: a pre and post implementation study*. Poster presented at American Society of Health System Pharmacists Midyear Meeting, 2015

Hatfield L, Biehle K. *Hypertonic Saline vs. Mannitol for Elevated Intracranial Pressure in Pediatric Traumatic Brain Injury*. Poster presented at Society of Critical Care Medicine Annual Critical Care Congress, 2011

Hatfield L. *Clinical Pharmacist Interventions and Medical Staff Perceptions of Pharmacy Services in a Teaching Hospital Emergency Department*. Poster presented at American Society of Health System Pharmacists Midyear Clinical Meeting, 2010

Hatfield L, Biehle K. *Medication History Interviews by Clinical Pharmacists in the Emergency Department: Impact on Medication Reconciliation*. Poster presented at Pediatric Pharmacy Advocacy

Group Annual Conference, 2010

Phanco LM. *Designing a Pharmacist Conducted Medication Reconciliation Program to Optimize Patient Care.* Poster presented at American Society of Health System Pharmacists Midyear Meeting, 2005

PODCASTS

Shenvi CL, **Hatfield LM**. *How to reverse oral anticoagulants*. GEMCAST**.** September 2016. Accessible at: https://gempodcast.com/2016/09/30/how-to-reverse-oral-anticoagulants

Shenvi CL, **Hatfield LM**. *High risk medications and adverse drug events*. GEMCAST. November 2015. Accessible at: https://gempodcast.com/2015/11/11/high-risk-medications-and-adverse-drug-events

TEACHING EXPERIENCE

Adjunct Assistant Professor of Clinical Education — Sept 2019- present
University of California San Francisco School of Pharmacy

Assistant Professor of Clinical Education — April 2012- July 2018
University of North Carolina Eshelman School of Pharmacy
- Emergency Medicine, Critical Care, Toxicology, Pediatrics
- Interprofessional Simulation-Based Education

Adjunct Instructor — Oct 2014- July 2018
University of North Carolina School of Medicine
Department of Emergency Medicine
- Pharmacology, Toxicology, Trauma, Cardiology, Anticoagulation Reversal, Infectious Disease, Behavioral Health

Adjunct Clinical Assistant Professor of Pharmacy Practice — June 2008- April 2012
Mercer University College of Pharmacy and Health Sciences

Adjunct Instructor — May 2008- April 2012
Emory University School of Medicine
Department of Emergency Medicine, Grady Health System

Full time non-tenure track clinical faculty, Department of Pharmacy Practice — July 2007- June 2008
Mercer University College of Pharmacy and Health Sciences
- Critical Care and Emergency Medicine

Adjunct Clinical Assistant Professor of Pharmacy Practice — Jan 2005-July 2007
University of California San Diego, Skaggs School of Pharmacy

Clinical Preceptor — Jan 2005- July 2007
University of the Pacific School of Pharmacy

AWARDS

2019 University of California San Francisco School of Pharmacy Master Preceptor Program

2018 UNC Medical Center and UNC Eshelman School of Pharmacy Preceptor of the Year
- Awarded to one preceptor annually at largest pharmacy residency program and #1 ranked pharmacy school in the US

2017 University of North Carolina Medical Center Emergency Medicine Employee of the Quarter

2016 American Society of Health- System Pharmacists Best Practice Award
- Awarded to six projects nationwide annually

2016 University of North Carolina Medical Center Pharmacy Residency Preceptor of the Year
- Awarded to one preceptor annually at largest pharmacy residency program in the US

2010 Children's Healthcare of Atlanta Pharmacy Preceptor of the Year

2008 Mercer University Friend of APhA-ASP Award
- Presented to one practitioner annually in recognition of outstanding service to students

2008 Georgia Pharmacists Association New Practitioner Leadership Award
- Presented to one new practitioner annually in recognition of outstanding leadership

2007 Naval Medical Center San Diego Allied Health Professional of the Year

2007 Naval Medical Center San Diego Pharmacy Preceptor of the Year

2005 American Pharmacists Association National Mortar and Pestle Professionalism Award
- Awarded to one new graduate nationally in recognition of excellence in pharmaceutical care, leadership, and professionalism

2004 Mercer University Griffin B. Bell Community Service Award
- Awarded to one graduate annually from all schools and colleges at Mercer University in recognition of superior leadership and community service

2004 Mercer University Mortar and Pestle Professionalism Award
- Awarded to one graduate annually in recognition of excellence in leadership, scholastic ability, and professionalism

2002 Unites States Navy Health Scholars Collegiate Program Scholar
- Selected as one of only 10 national recipients of scholarship and resultant officer commission in the U.S. Navy for excellence in academics, community service, leadership potential, physical readiness, and patriotism

1998 Willingham Tift Fellowship at Mercer University
- Awarded to one new student annually in recognition of excellence in leadership, community service, and academic achievement

CERTIFICATIONS

LEAN Six Sigma Yellow Belt, Purple Belt	2014- present
Crisis Prevention Institute Provider	2014- present
Pediatric Advanced Life Support Instructor	2010- 2019
Advanced Cardiac Life Support Instructor	2010- 2019
Advanced Cardiac Life Support Provider	2004- present
Advanced Trauma Life Support (audit)	2008- present

PROFESSIONAL MEMBERSHIPS AND ACTIVITIES

United States Agency for International Development 2017- present
- Clinical Guideline Reviewer

National Expert Advisory Committee 2015-present
Improving Pediatric Sepsis Outcomes
Children's Hospital Association

Peer Reviewer- Emergency Medicine and Toxicology Subject Matter
- *Pharmacotherapy* 2011-present
- ACCP Pharmacotherapy Board Certification Program 2010- present

American College of Clinical Pharmacy 2006- present
- Emergency Medicine PRN Member

American Society of Health System Pharmacists 2004- present
- Emergency Medicine Special Advisory Group Panel

Phi Lambda Sigma Pharmacy Leadership Society 2003- present

American Pharmacists Association 2000- 2008
- Mercer University Faculty Advisor, 2007-2008
- National APhA-ASP Standing Committee Chair, 2004
- Mercer University Chapter President, 2003

MILITARY DECORATIONS

Navy and Marine Corps Commendation Medal
National Defense Service Medal
Global War on Terrorism Service Medal
Navy and Marine Good Conduct Medal

COMMUNITY AND PERSONAL SERVICE

Board of Directors 2015- 2018
University Child Care Center, Chapel Hill, NC
- Chairman 2016-2017

Volunteer 2012- 2018
Student Health Action Coalition Clinic for the Homeless

Alumnae Board of Directors 2013- 2016
Mercer University College of Pharmacy and Health Sciences

Join ISMP on Tuesday evening, **December 10, 2019**, at 6:00 p.m. for the 22nd Annual **Cheers Awards** at **Stoney's Rockin' Country** in Las Vegas. The gala will celebrate a group of health-care leaders who have gone all in to develop best practices and programs that prevent medication errors and protect patients.

Please Attend the Awards Dinner and/or Make a Donation to Support ISMP's Efforts

You can help honor this year's **Cheers Award** winners as well as recognize **ISMP's 25th anniversary** by making a donation and/or attending the awards dinner. Your participation helps bring attention to safety advances and enables ISMP to continue the core of its lifesaving work—preventing medication errors. To make a donation and/or register for the dinner, please visit: www.ismp.org/node/938.

Keynote Speaker:
Marcus Schabacker, MD, PhD

President and Chief Executive Officer, ECRI Institute, Plymouth Meeting, PA

Lifetime Achievement Award Winner:
Rita Shane, PharmD, FASHP, FCSHP

Chief Pharmacy Officer and Professor of Medicine, Cedars-Sinai Medical Center, Los Angeles, CA

ISMP Activities at the 2019 ASHP Midyear Meeting in Las Vegas

Workshop *(preregistration required - please call 215-947-7797)*

Friday, December 6 & Saturday, December 7
Medication Safety Intensive
Maggiano's Little Italy
Fashion Show Mall, 3200 Las Vegas Blvd., Las Vegas, NV
To register, go to: www.ismp.org/node/1239

Symposia *(all at Mandalay Bay North Convention Center)*

Tuesday, December 10
Justifying Your Return on Investment with Integrated Medication Use Technology
11:30 a.m. – 1:00 p.m., Doors open at 10:45 a.m.
Room: Islander Ballroom G, Lower Level
To register, go to: www.ismp.org/node/12306

Wednesday, December 11
Transforming Smart Infusion Pump Safety: Paving the Way with the New ISMP Guidelines
11:30 a.m. – 1:00 p.m., Doors open at 10:45 a.m.
Room: South Pacific J, Lower Level
To register, go to: www.ismp.org/node/12610

Educational Sessions with ISMP Speakers
(all at Mandalay Bay South Convention Center)

Sunday, December 8
Small but Mighty: Improving Safety with High-Alert Medications
2:30 p.m. – 3:30 p.m.
Room: Oceanside B, Level 2

Tuesday, December 10
The Safety of Intravenous Drug Delivery Systems: Update on Issues Since the 2009 Consensus Development Conference
2:00 p.m. – 3:30 p.m.
Room: Lagoon F, Level 2

Managing the Crisis You Didn't Prevent: Leadership and Medication Safety
4:00 p.m. – 5:15 p.m.
Room: South Seas J, Level 3

Wednesday, December 11
ISMP Medication Safety Update for 2020
8:00 a.m. – 9:30 a.m.
Room: Oceanside B, Level 2

ISMP

For more information: www.ismp.org or call 215-947-7797
Visit ISMP at Exhibit Booth # 667


Country
AF RADIO

CHOMP ED FREE Naloxone Guideline

As we all know, new state legislation has mandated that we offer a prescription for naloxone for patients at risk of overdose.

However, not all patients have insurance, and some of our uninsured patients have no access to a pharmacy, or cannot afford the $150 that a Nasal Naloxone kit costs.

So, thanks to a grant from the CA Dept of Health Care Services, we now are able to give patients Naloxone FREE in the ED before discharge.

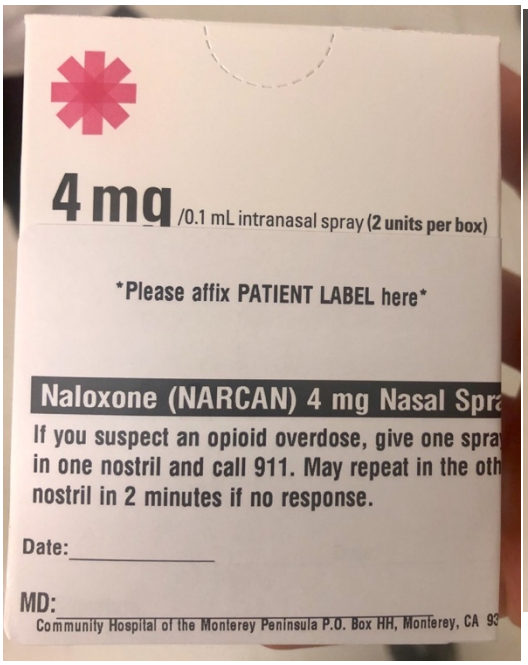
Who should receive Naloxone FREE in the ED before discharge?

Patients who cannot pay for or fill a prescription for naloxone:

- Homeless patients staying in a remote area without transportation (such as in the woods)
- Patients at risk for overdose without insurance

How do I provide a patient with free Naloxone in the ED before discharge?

1. Tell the ED RN that you need a naloxone kit for discharge for an ED patient
2. The naloxone kit is now in the ED Pyxis, and can be removed to give to the patient
3. The naloxone kit has a sticker on it that you need to fill out with the date and your name as the prescribing MD. The sticker has directions for the patient on it (see below)
    a. Note that the sticker on the Naloxone kit has a space for a "PATIENT LABEL". Please place a patient label (a sticker with the patient's information on it) from the patient's chart here
4. Please document (or have your scribe document) in EPIC that the patient could not fill a prescription for naloxone, and that you have given the patient a discharge naloxone kit. Please document the lot number and expiration date for the kit in your ED note. This information can be found on the top of the box (see below)
5. Please provide education to the patient on their naloxone. You can use the dotphrase .EDUNALOXONEFREE



PURPOSE

To describe the process by which Naloxone Nasal inhalers are procured, stored, evaluated for use, dispensed to patients by physicians and documented. Additionally, this policy will describe the process of patient and family education of the use of the product.

POLICY

A. Naloxone Nasal inhalers are not a formulary item at CHOMP. Physician dispensing of Naloxone Nasal inhalers will be dependent upon grant-procurement of the medication from an outside source.

B. Naloxone Nasal inhalers will not be used in the inpatient areas and they will only be dispensed by emergency room physicians to patients registered and seen in the Emergency Department.

C. Proper storage, inventory control, ordering, documentation, education and dispensing will be done by physician staff.

PROCEDURE

A. Naloxone Nasal inhalers will be obtained directly from a manufacturer pursuant to a grant awarded by an outside organization. In the event the grant awarded expires, or if the Emergency Department runs out of Naloxone Nasal inhalers, CHOMP pharmacy will not procure any additional stock.

B. Inventory that is obtained will be checked in with the lot number, expiration date, date of receiving and number of prescriptions received.

C. Inventory will be stored in secured area. A perpetual inventory of stock will be maintained. Access to the inventory will be limited to physician and pharmacy staff.

D. Criteria for use of Naloxone Nasal inhalers will be determined by physician staff, and will include the following:

    1. The patient is at-risk for opiate overdose by either prescribed or illicit use of narcotics.

    2. The patient is unlikely to obtain a prescription for Naloxone Nasal inhaler from an outside pharmacy due to either financial issues or non-compliance issues.

    3. The patient has received education for Naloxone Nasal inhaler usage either by the prescribing physician or supervised by the ordering physician. If appropriate, a family member or care provider of the patient may be given the patient education.

E. The physician or authorized prescriber must dispense the medication directly to the patient, or if appropriate, to a family member or caregiver.

F. An order for the Naloxone Nasal inhaler must be documented on the patient’s electronic health record.

G. The Naloxone Nasal inhaler must be labelled with the following information: patient name (a patient label will be adequate), name and strength of drug, date of dispensing and physician dispensing naloxone inhaler.

H. Physicians and authorized prescribers who work in the emergency department must be trained by the physician champion in all applicable procedures regarding Naloxone Nasal inhalers prior to ordering and dispensing the inhalers. Licensed staff that may give Naloxone Nasal Spray education under the supervision of the dispensing physician must be trained by the physician champion regarding the product education.

APPENDICES

Appendix A: Naloxone Fact Sheet English Version

Appendix B: Naloxone Fact Sheet Spanish Version

Appendix C: Questions about Naloxone (English Version)

Appendix D: Questions about Naloxone (Spanish Version)

Appendix E: Product label to be Placed on Naloxone Nasal Spray Packaging

CONTENTS	DESCRIPTION
Submitted by:	Pharmacy Department
Next review date:	2021
Effective date:	
Applicable to:	All CHOMP departments
Approved by:	Pharmacy and Therapeutics Committee: Medical Executive Committee: Interdisciplinary Quality Committee:
Reviewed by:	Pharmacy Managers
Replaces:	NEW
References:	
Key Words	Naloxone, dispensing, physician
Distribution:	
Additional information:	Available on CHOMP Intranet
Related policies or programs	

Appendix A

Naloxone Fact Sheet English Version

What is an opioid overdose?

Opioids can cause bad reactions that make your breathing slow or even stop. This can happen if your body can't handle the opioids that you take that day.

TO AVOID AN ACCIDENTAL OPIOID OVERDOSE:

- Try not to mix your opioids with alcohol, benzodiazepines (Xanax, Ativan, Klonopin, Valium), or medicines that make you sleepy.
- Be extra careful if you miss or change doses, feel ill, or start new medications.

Now that you have naloxone...

Tell someone where it is and how to use it.

Common opioids include:

GENERIC	BRAND NAME
Hydrocodone	Vicodin, Lorcet, Lortab, Norco, Zohydro
Oxycodone	Percocet, OxyContin, Roxicodone, Percodan
Morphine	MSContin, Kadian, Embeda, Avinza
Codeine	Tylenol with Codeine, TyCo, Tylenol #3
Fentanyl	Duragesic, Actiq
Hydromorphone	Dilaudid
Oxymorphone	Opana
Meperidine	Demerol
Methadone	Dolophine, Methadose
Buprenorphine	Suboxone, Subutex, Zubsolv, Bunavail, Butrans

* Heroin is also an opioid.

For patient education, videos and additional materials, please visit **www.prescribetoprevent.org**

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

2016

Opioid safety and how to use naloxone

A GUIDE FOR PATIENTS AND CAREGIVERS

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

In case of overdose:

1 Check reponsiveness

Look for any of the following:

- No reponse even if you shake them or say their name
- Breathing slows or stops
- Lips and fingernails turn blue or gray
- Skin gets pale or clammy

2 Call 911 and give naloxone

If no reaction in 3 minutes, give second naloxone dose

3 Do rescue breathing and/or chest compressions

Follow 911 dispatcher instructions

>> STAY WITH PERSON UNTIL HELP ARRIVES.

How to give naloxone:

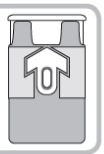
There are 4 common naloxone products. Follow the instructions for the type you have.

Nasal spray

This nasal spray needs no assembly and can be sprayed up one nostril by pushing the plunger.

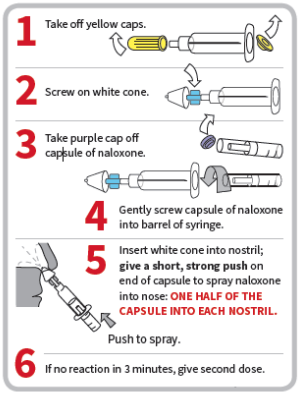
Auto-injector

The naloxone auto-injector needs no assembly and can be injected into the outer thigh, even through clothing. It contains a speaker that provides step-by-step instructions.



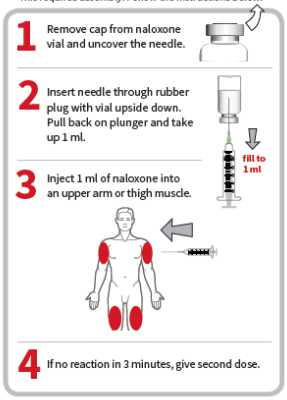
Nasal spray with assembly

This requires assembly. Follow the instructions below.



Injectable naloxone

This requires assembly. Follow the instructions below.



Appendix B

Naloxone Fact Sheet Spanish Version

¿Qué es una sobredosis de opioides?

Los opioides pueden causar malas reacciones haciendo que su respiración sea más lenta o incluso se detenga. Esto podría suceder si su cuerpo no es capaz de soportar los opioides que haya tomado ese día.

PARA EVITAR UNA SOBREDOSIS ACCIDENTAL DE OPIOIDES:

- Trate de no mezclar sus opioides con alcohol, benzodiazepinas (Xanax, Ativan, Klonopin, Valium), ni medicamentos que le produzcan somnolencia.
- Tenga mucho cuidado si se le olvida tomar una dosis o la modifica, si se siente enfermo o empieza a tomar un nuevo medicamento.

Ahora que cuenta con naloxona...

Dígale a alguien en dónde está y cómo utilizarla.

Los opioides comunes incluyen:

GENÉRICO	MARCA
Hidrocodona	Vicodin, Lorcet, Lortab, Norco, Zohydro
Oxicodona	Percocet, OxyContin, Roxicodone, Percodan
Morfina	MSContin, Kadian, Embeda, Avinza
Codeína	Tylenol with Codeine, TyCo, Tylenol #3
Fentanilo	Duragesic, Actiq
Hidromorfona	Dilaudid
Oximorfona	Opana
Meperidina	Demerol
Metadona	Dolophine, Methadose
Buprenorfina	Suboxone, Subutex, Zubsolv, Bunavail, Butrans

* La heroína también es un opioide.

Para obtener materiales educativos para pacientes, como videos y demás, visite **www.prescribetoprevent.org**

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

2016

Seguridad en el uso de opioides y administración de naloxona

UNA GUÍA PARA PACIENTES Y ENCARGADOS DEL CUIDADO

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

En caso de sobredosis:

1 Verifique si la persona reacciona

Esté atento a los siguientes síntomas:

- No reacciona, así la sacuda o grite su nombre
- La respiración se hace más lenta o se detiene
- Los labios y las uñas se vuelven azules o grises
- La piel se torna pálida o sudorosa

2 Llame al 911 y administre la naloxona

Si no hay ninguna reacción en 3 minutos, administre una segunda dosis de naloxona

3 Comience a dar respiración de boca a boca o compresiones cardíacas

Siga las instrucciones del operador del 911

>> PERMANEZCA CON LA PERSONA HASTA QUE LLEGUE LA AYUDA

CÓMO ADMINISTRAR LA NALOXONA:

Hay cuatro productos de naloxona comunes. Siga las instrucciones del tipo con el que cuenta.

Aerosol nasal

Este aerosol nasal no necesita ser ensamblado. Se administra empujando el émbolo dentro de una fosa nasal.

Inyector automático

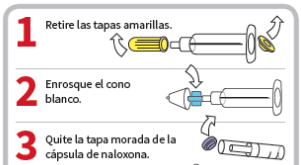
El inyector automático de naloxona no necesita ser ensamblado y puede inyectarse en la parte exterior del muslo, incluso a través de la ropa. Contiene un parlante que da instrucciones paso a paso.

Aerosol nasal (ensamblado)

Este producto requiere ser ensamblado. Siga las siguientes instrucciones:

1. Retire las tapas amarillas.
2. Enrosque el cono blanco.
3. Quite la tapa morada de la cápsula de naloxona.
4. Enrosque suavemente la cápsula de naloxona en el cilindro de la jeringa.
5. Inserte el cono blanco en la fosa nasal; **empuje con un movimiento breve y enérgico** el extremo de la cápsula para rociar la naloxona dentro de la nariz. **MEDIA CÁPSULA EN CADA FOSA NASAL.**

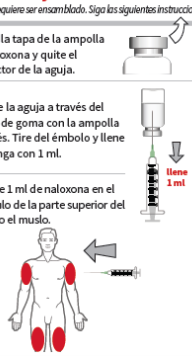
   Empuje para rociar.
6. Si no hay ninguna reacción en 3 minutos, administre una segunda dosis.



Naloxona inyectable

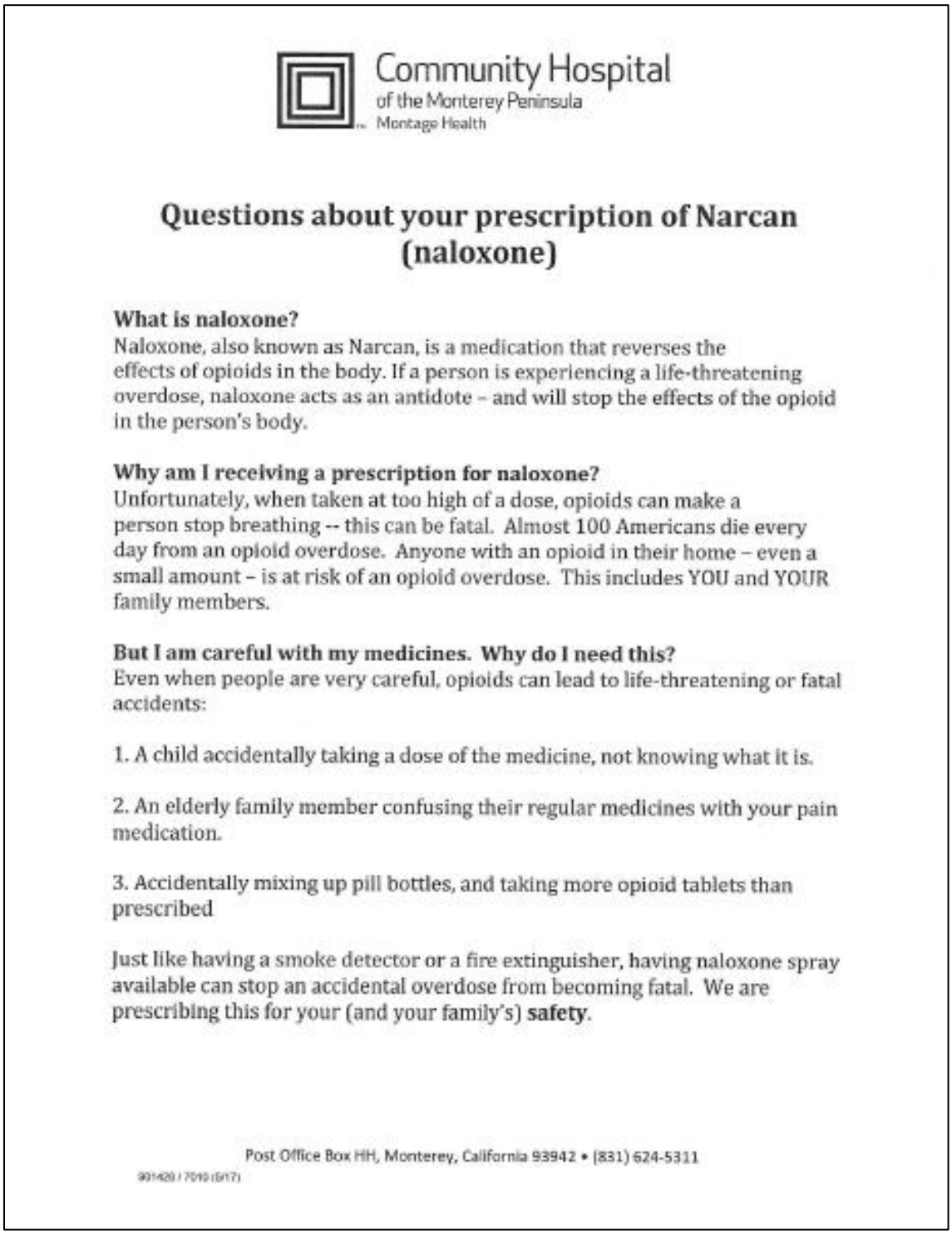
Este producto requiere ser ensamblado. Siga las siguientes instrucciones:

1. Retire la tapa de la ampolla de naloxona y quite el protector de la aguja.
2. Inserte la aguja a través del tapón de goma con la ampolla al revés. Tire del émbolo y llene la jeringa con 1 ml.
3. Inyecte 1 ml de naloxona en el músculo de la parte superior del brazo o el muslo.
4. Si no hay ninguna reacción en 3 minutos, administre una segunda dosis.



Appendix C

Questions about Naloxone (English Version)



Community Hospital
of the Monterey Peninsula
Montage Health

Questions about your prescription of Narcan (naloxone)

What is naloxone?
Naloxone, also known as Narcan, is a medication that reverses the effects of opioids in the body. If a person is experiencing a life-threatening overdose, naloxone acts as an antidote – and will stop the effects of the opioid in the person's body.

Why am I receiving a prescription for naloxone?
Unfortunately, when taken at too high of a dose, opioids can make a person stop breathing -- this can be fatal. Almost 100 Americans die every day from an opioid overdose. Anyone with an opioid in their home – even a small amount – is at risk of an opioid overdose. This includes YOU and YOUR family members.

But I am careful with my medicines. Why do I need this?
Even when people are very careful, opioids can lead to life-threatening or fatal accidents:

1. A child accidentally taking a dose of the medicine, not knowing what it is.

2. An elderly family member confusing their regular medicines with your pain medication.

3. Accidentally mixing up pill bottles, and taking more opioid tablets than prescribed

Just like having a smoke detector or a fire extinguisher, having naloxone spray available can stop an accidental overdose from becoming fatal. We are prescribing this for your (and your family's) **safety**.

Post Office Box HH, Monterey, California 93942 • (831) 624-5311

901420 / 7010 (5/17)

Appendix D

Questions about Naloxone (Spanish Version)

Community Hospital
of the Monterey Peninsula
Montage Health

Preguntas acerca de su receta médica para Narcan (naloxone)

¿Qué es naloxone?

Naloxone, también conocido como Narcan, es un medicamento que invierte los efectos de los opioides en el cuerpo. Si una persona experimenta una sobredosis que pone en peligro su vida, naloxone actúa como un antídoto – y hará que paren los efectos del opioide en el cuerpo de esa persona.

¿Por qué estoy recibiendo una receta médica para naloxone?

Desafortunadamente, cuando se toman en dosis demasiado altas, los opioides pueden hacer que una persona deje de respirar -- esto puede causar la muerte. Casi 100 americanos mueren diariamente por sobredosis de opioides. Cualquier persona que tenga un opioide en su hogar – aun en pequeñas cantidades – corre el riesgo de una sobredosis de opioides. Esto le incluye a USTED y a los miembros de SU familia.

Pero yo sí tengo cuidado con mis medicinas. ¿Por qué necesito esto?
Los opioides pueden llevar a accidentes que ponen la vida en peligro o incluso causan la muerte, aun cuando las personas tienen mucho cuidado:

1. Un niño o niña que toma una dosis del medicamento, sin saber qué es.
2. Un familiar de edad avanzada que confunde los medicamentos que él o ella toma con los medicamentos para el dolor que usted toma.
3. Confundir los frascos de pastillas accidentalmente y tomar más tabletas de opioide de lo que le recetaron.

Es como tener un detector de humo o un extinguidor de incendios, tener el spray de naloxone disponible puede evitar que una sobredosis accidental cause la muerte. Le estamos recetando esto para su **seguridad** (y la de su familia).

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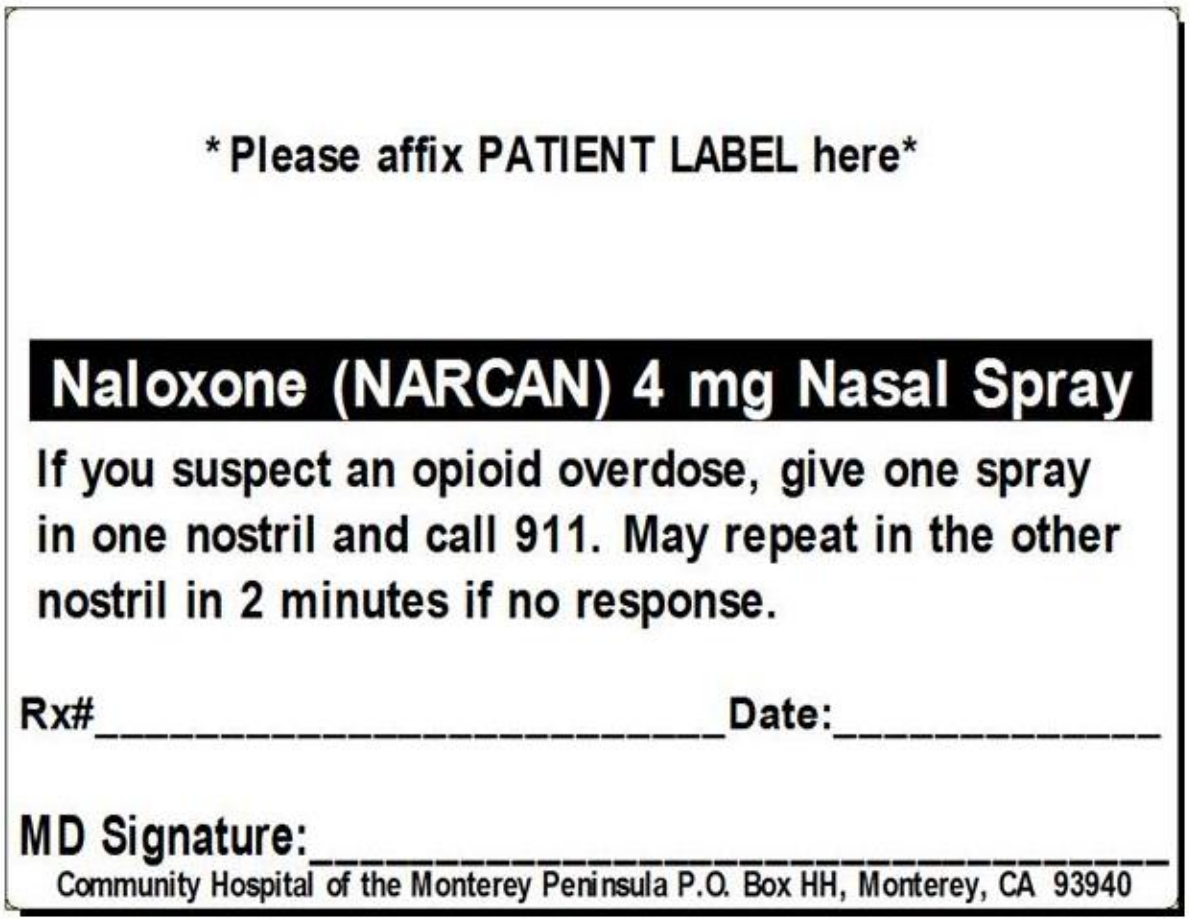
901428 / 7010 (5/17)

Appendix E

Product Label to be Placed on Naloxone Nasal Spray Packaging



FDA STATEMENT

Statement on FDA's new report regarding root causes and potential solutions to drug shortages

For Immediate Release:

October 29, 2019

Statement From:

Acting Commissioner of Food and Drugs - Food and Drug Administration
Norman E. "Ned" Sharpless MD
Director - Center for Drug Evaluation and Research
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One of the U.S. Food and Drug Administration's top priorities is to ensure that Americans have access to safe and effective medicines. Sometimes, for a number of reasons, shortages (/drugs/drug-safety-and-availability/drug-shortages) of certain medicines occur and the FDA works immediately with our public health partners and industry to minimize their impact on patients and restore the availability of these drugs. A shortage of just one critical drug can have a major impact on a patient's health, which underscores why government and industry need to act quickly to prevent future shortages.

Despite public- and private-sector efforts to prevent and mitigate drug shortages, they continue to occur and persist. So, at the request of Congress last year, the FDA convened an inter-agency Drug Shortages Task Force (/drugs/drug-shortages/agency-drug-shortages-task-force) to study the problem, determine the root causes of drug shortages, and make recommendations for enduring solutions. This effort was designed to help address the number of drug shortages that we continue to experience, which place a serious burden on patients and providers who need access to these medically necessary products.

To understand forces causing drug shortages, the Task Force commissioned a team of FDA economists and scientists to analyze drugs that went into shortage from 2013 to 2017. The agency also invited public participation by hosting a public meeting, opening a docket to receive public comments, and inviting stakeholders from industry, academia, and the medical provider and patient communities to a series of listening sessions to provide insight into the causes of drug shortages and identify potential solutions.

Today, on behalf of the inter-agency Task Force, the FDA issued a report, "Drug Shortages: Root Causes and Potential Solutions (/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions)," that attempts to identify root causes and offer recommendations for

government and industry based on insights gleaned from stakeholders in the private and public sectors. These recommendations are intended to help prevent and mitigate future drug shortages. The report focuses on human drugs, but many of the same concerns apply to veterinary medicines used to treat service, companion, and food-producing animals.

The Task Force found that the number of ongoing drug shortages has been rising, and that their impact is likely underappreciated. The Task Force analyzed 163 drugs that went into shortage from 2013 to 2017 and compared these medicines to similar drugs that did not go into shortage. Shortage drugs were more likely to be relatively low-price and financially unattractive drugs and were more likely to be sterile injectables. Shortages often occurred as a result of disruption in supply due to a variety of factors. Importantly, prices rarely rose after shortages began, and during shortages, production typically did not increase enough to restore supply to pre-shortage levels. Many manufacturers reported discontinuing the production of drugs before a shortage for commercial reasons (e.g., loss of profitability). These results suggest a broken marketplace, where scarcity of drugs in shortage or at risk for shortage does not result in the price increases predicted by basic economic principles. While there are no easy solutions to the problems identified, and there is no single cause of drug shortages, the Task Force offers three key recommendations to address the root causes of shortages.

First, we recommend taking steps to increase understanding of the impacts of drug shortages and companies' contracting practices that may contribute to them. Currently, there is little private- or public-sector effort to collect and analyze comprehensive information to characterize shortages, quantify their effects, or closely observe the contracting practices that may be driving them. This information would help improve stakeholders' understanding of the impact shortages have on the Nation's health care and support private- and public-sector strategies to prevent or mitigate them in the future. Our report encourages more systematic and transparent study of current contracting practices to support development of model contracts designed to promote reliable access to safe, effective, and affordable drugs.

Second, we support the idea of developing a system to measure and rate a facility's quality management maturity. The rating would evaluate the robustness of a manufacturing facility's quality system and its ability to deliver high-quality products reliably and without disruption. Historically, many pharmaceutical manufacturing firms have focused their efforts on compliance with Current Good Manufacturing Practices (CGMPs), which set a minimum threshold that companies must achieve to be allowed to supply the U.S. marketplace. They do not include more advanced levels of quality management. As outlined in an FDA Voices perspective piece issued last week (/news-events/fda-voices-perspectives-fda-leadership-and-experts/help-reduce-drug-shortages-we-need-manufacturers-sell-quality-not-just-medicine), a rating system could be used to inform purchasers, group purchasing organizations (GPOs), and consumers about the state of, and commitment to, the quality management maturity of the manufacturing facility making the drugs they are buying. This effort would introduce

transparency into the market, and provide companies committed to quality management maturity with a competitive advantage, potentially enabling them to obtain sustainable prices as well as grow market share.

Third, we recommend considering new contracting approaches that help ensure a reliable supply of drugs. This may include providing financial incentives to make certain that manufacturers, especially of older generic drugs, earn sustainable returns on their products. The combination of more complete information about contracting practices and greater transparency of the quality management maturity of specific manufacturing sites would enable payers, purchasers, and GPOs to consider new contracting approaches aimed at making sure there is a reliable supply of medically important drugs. This could be done through several different mechanisms, such as paying higher prices for drugs manufactured at top-rated facilities, requiring a certain quality maturity rating as a condition of contracting, or guaranteeing purchase of a set volume of products from sites achieving a certain quality maturity rating.

The report also describes several legislative proposals and planned FDA initiatives that focus primarily on enabling the agency to help prevent supply disruptions that lead to shortages. These include new requests in the President's FY 2020 budget and new guidances that the agency intends to release by the end of calendar year 2019. We have outlined these specific actions in the report, and they are designed to mitigate and prevent drug shortages nationwide.

We also feel that international action is necessary. The International Council for Harmonisation (https://www.ich.org/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (ICH) is finalizing a guideline, "ICH Guideline Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management (https://database.ich.org/sites/default/files/Q12_EWG_Draft_Guideline.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)," which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process. Global implementation of this guideline, once finalized, could facilitate the efforts of manufacturers for the international market who wish to modernize processes and equipment to avoid potential disruptions, but have found the regulatory landscapes of different countries to pose a financial burden.

Given the potential scale of impacts from drug shortages, and the fact that these impacts have continually been underestimated, it is likely that drug shortages will continue to persist absent major changes to this marketplace. The root causes of shortages involve economic factors that are driven by both private- and public-sector decision-making. This means that the types of enduring solutions proposed in the report will require multi-stakeholder efforts and rethinking business practices throughout all sectors of the health care system. It will also require a fuller characterization of the true costs of shortages and more comprehensive and reliable analysis of the effects shortages have on patients and the health care system.

We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers. In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need. The FDA will continue to report regularly on the progress of our Task Force and keep the public informed about current drug shortages and our efforts to prevent and mitigate new ones.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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- Animal Drug Shortage Information (/animal-veterinary/product-safety-information/animal-drug-shortage-information)
- FDA Voices: To Help Reduce Drug Shortages, We Need Manufacturers to Sell Quality — Not Just Medicine (/news-events/fda-voices-perspectives-fda-leadership-and-experts/help-reduce-drug-shortages-we-need-manufacturers-sell-quality-not-just-medicine)

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Drug Shortages:

Root Causes and Potential Solutions

2019

Executive Summary

FDA U.S. FOOD & DRUG ADMINISTRATION

ACKNOWLEDGMENTS

This report is based on work of a Federal task force chaired by the U.S. Food and Drug Administration (FDA). FDA is grateful for the valuable contributions of all participating and consulting agencies and for their assistance in developing this report. The full version of this report is available on the FDA website at http://www.fda.gov/media/131130/download.

FDA thanks the following agencies for their participation in the Drug Shortages Task Force:

• *Centers for Medicare and Medicaid Services, Department of Health and Human Services*

• *Department of Defense*

• *Department of Veterans Affairs*

• *Federal Trade Commission*

• *Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services*

FDA thanks the following agencies for consultations in preparing this report:

• *Defense Advanced Research Projects Agency*

• *U.S. Department of the Treasury*

• *Drug Enforcement Administration, U.S. Department of Justice*

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• *Office of the Commissioner*

• *Center for Drug Evaluation and Research*
- *Office of the Center Director*
- *Office of Compliance*
- *Office of Executive Programs*
- *Office of Generic Drugs*
- *Office of Pharmaceutical Quality*
- *Office of Regulatory Policy*
- *Office of Strategic Programs*

• *Center for Biologics Evaluation and Research*

• *Center for Devices and Radiological Health*

• *Center for Veterinary Medicine*

• *Office of Regulatory Affairs*

A Report by the Drug Shortages Task Force

2019 Executive Summary

Drug Shortages:

Root Causes and Potential Solutions

The full version of this report is available on the FDA website at http://www.fda.gov/media/131130/download

Drug Shortages Pervade Many Aspects of Patient Care

Shortages can worsen patients' health outcomes by causing delays in treatment or changes in treatment regimens, such as substituting less effective therapies, when a drug of choice is not available. Even when alternatives to the preferred drug are available, a patient's care may be compromised. According to a recent study, 56 percent of hospitals reported they had changed patient care or delayed therapy in light of drug shortages; 36.6 percent said they had rescheduled non-urgent or emergent procedures.

Childhood Cancer

Drug shortages can have a drastic impact on the most vulnerable patients. An estimated 90 percent of the 3,000 children afflicted with T-cell acute lymphoblastic leukemia (ALL) are curable (5-year event-free survival). However, many of the drugs used to treat children with ALL (the most common childhood cancer) are older drugs, potentially making them more vulnerable to shortage. From 2009-2019, 9 of the 11 drugs used to treat ALL were in and out of shortage. Despite recent evidence that adding nelarabine to children's treatment regimens improves survival rates and is thus becoming the new standard of care, nelarabine has been in shortage recently, causing much anguish and grief for patients, parents, and clinicians.

"I am caring for a 12-year-old girl with newly diagnosed T-cell acute lymphoblastic leukemia. As soon as the diagnosis was confirmed, I reached out to pharmacy colleagues who confirmed that our hospital had no nelarabine. Nelarabine was recently proven to improve survival in children like my patient with T-cell ALL. Through their herculean efforts, enough nelarabine was secured for at least the first cycle of treatment. It remains to be seen whether we will be able to obtain enough drug for subsequent cycles."

— Yoram Unguru, MD, MS, MA, The Children's Hospital at Sinai, Johns Hopkins Berman Institute of Bioethics

Septic Shock

A shortage of norepinephrine in 2011 led to some patients with septic shock being treated with alternative drugs. When patients with septic shock were admitted to hospitals experiencing the shortage, they were more likely to die than at hospitals not experiencing the shortage.

Palliative Care

Bleomycin is used for palliative treatment of a number of forms of cancer including Hodgkin and non-Hodgkin lymphoma. In 2016, a severe shortage of bleomycin led to use of alternative treatment regimens. Although just as effective, the alternatives require inpatient stay, increasing stress for patients and families, potentially exposing patients to pathogens in the hospital environment, and substantially increasing costs.

Anesthesia and Sedation

Drug omissions due to shortages negatively impact patient care and the patient experience. Lidocaine is used to diminish the burning sensation often associated with propofol, a common anesthetic. The American Association of Nurse Anesthetists reports that a lidocaine shortage has resulted in patients who receive propofol feeling a burn on induction, leading to agitation at precisely the time a patient should be relaxed and without stress as they undergo sedation or anesthesia.

Drug Shortages: Root Causes and Potential Solutions

2019 Executive Summary

In June 2018, a bipartisan group of 31 U.S. Senators and 104 members of the House of Representatives wrote to Scott Gottlieb, MD, then Commissioner of Food and Drugs, to ask for assistance in addressing the Nation's drug shortage crisis. Their letters urged the Food and Drug Administration (FDA or "the Agency") to convene a task force to study the problem, prepare a report on the root causes of drug shortages, and make recommendations for enduring solutions. The full version of this report is available on the FDA website at http://www.fda.gov/media/131130/download.

In response to this request from Congress, the FDA convened an inter-agency Drug Shortages Task Force ("Task Force") of senior officials drawn from its own ranks and several partner Federal agencies.[1] The Agency invited public participation through a public meeting on November 27, 2018 with a docket to receive comments, and invited stakeholders to a series of listening sessions. The Task Force commissioned a team of FDA economists and other scientists to analyze drugs that went into shortage between calendar years 2013-2017 with a view to understanding the underlying forces that were driving them. The analysts relied on the statutory definition of drug shortage, as a period of time when the demand or projected demand for the drug within the U.S. exceeds the supply.[2] The Agency is now issuing this report containing the Task Force's analysis of root causes and recommendations for addressing them. Although the focus of the report is on human drugs,[3] many of the same concerns apply to veterinary medicines used to treat service, companion, and food-producing animals.[4]

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1. The Drug Shortages Task Force brings together officials not only from the U.S. Food and Drug Administration, but also from several partner agencies including the Centers for Medicare and Medicaid Services, the Department of Defense, the Department of Veterans Affairs, the Federal Trade Commission, and the Office of the Assistant Secretary for Preparedness and Response within the Department of Health and Human Services (HHS). In addition, the Task Force consulted with officials from the Defense Advanced Research Projects Agency, the U.S. Department of the Treasury, and the Drug Enforcement Administration within the U.S. Department of Justice. This Task Force is not to be confused with a previously established drug shortage task force, which was formed in 2012 to implement some provisions of FDASIA and has focused its activities on preventing and mitigating actual drug shortages.
2. The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines a "drug shortage" as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." FD&C Act s. 506C(h)(2) (21 U.S.C. 356c(h)(2)). The statutory definition of "drug shortage" is not limited to medically necessary drugs.
3. Section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)) provides that the term "drug" means: "(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C)."
4. Under certain conditions, the Animal Medicinal Drug Use Clarification Act of 1994 allows for the use of approved human drugs in animals. Because veterinarians, especially those in the companion animal field, often use human drugs in their patients, shortages of human drugs can affect veterinary medicine.

As the Congressional letters noted, drug shortages, including those that arise during emergencies, have been a persistent problem despite public and private sector efforts to prevent and mitigate them. Analysis presented by FDA at the November 2018 public meeting showed that the number of ongoing drug shortages has recently been increasing after declining from a peak in 2011, and drug shortages have been lasting longer, in some cases more than 8 years. FDA analyzed 163 drugs that went into shortage in the 5-year period between 2013 and 2017. Of the 163 drugs[5] in the sample, 63 percent (103) were drugs administered by injection ("sterile injectables") and 67 percent (109) were drugs that have a generic version on the market.[6] They were also older drugs, with a median time since first approval of almost 35 years. After many years off patent, the injectables typically were sold at relatively low prices. In the year prior to going into shortage, the median per unit price was $8.73 for all the shortage drugs, $11.05 for injectables, and $2.27 for orally administered drugs.[7, 8]

Information from health care providers, patients, and research studies suggests that the clinical and financial effects of shortages are substantial.

Information from health care providers, patients, and research studies suggests that the clinical and financial effects of shortages are substantial. However, comprehensive data about these effects are lacking and FDA believes that some recent attempts to quantify the impacts have underestimated them. Purchasers need more information on the clinical and financial impacts of shortages on patients and health care delivery to make informed buying decisions, which could play a role in preventing and mitigating drug shortages. Having high-quality quantitative data would help determine which strategies, or combinations thereof, would prove most useful in addressing the problem.

5. For purposes of this analysis, FDA defined a drug as a unique combination of active ingredient(s), route of administration, and dosage form — potentially grouping together multiple strengths, types of packaging, and manufacturers. These 163 drugs corresponded to 130 shortages as defined by FDA.
6. About half (47 percent) of the 163 drugs studied that went into shortage between 2013 and 2017 were both generics and sterile injectables.
7. FDA analysis of IQVIA data. The prices are the average 12-month price prior to the shortage start date with a 3-month leave-out period. The prices are inflation-adjusted to August 2018 based on the Producer Price Index for Pharmaceuticals. Per unit means per injection for injectables, and per pill or capsule for orally administered drugs. IQVIA, formerly Quintiles and IMS Health, Inc., is an American multinational company serving the combined industries of health information technology and clinical research.
8. These percentiles were calculated by comparing the earlier prices of shortage drugs to the prices of all other drugs with the same dosage form sold during that period. The aggregate numbers are then the mean of these percentiles within each group (injectables, orally administered, all drugs).

ECONOMIC FORCES ARE THE ROOT CAUSES OF DRUG SHORTAGES

Drug shortages persist because they do not appear to resolve according to the "textbook" pattern of market response. In this more typical pattern, prices rise after a supply disruption and provide an incentive for existing and new suppliers to increase production until there is enough supply of a product to meet demand. In this respect, the market for prescription drugs and especially generic drugs differs from other markets. A prime question that the Task Force sought to answer is, why does the drug market differ?

After reviewing the FDA analysis, published research studies, and stakeholder input, the Task Force identified three major root causes:

- ***Root Cause 1: Lack of Incentives to Produce Less Profitable Drugs.*** When market conditions limit manufacturers' profitability, they reduce a firm's motivation to maintain a presence in, or enter the market for older prescription drugs, and to invest in manufacturing quality and redundant capacity. Manufacturers of older generic drugs, in particular, face intense price competition, uncertain revenue streams, and high investment requirements, all of which limit potential returns. Current contracting practices contribute to a "race to the bottom" in pricing.

- ***Root Cause 2: Market Does Not Recognize and Reward Manufacturers for Mature Quality Management Systems.*** All manufacturers must meet regulatory requirements for adherence to Current Good Manufacturing Practices (CGMPs), which set a minimum threshold that companies must achieve in order to be allowed to supply the U.S. marketplace. Mature quality management, however, starts with a foundational quality management system that conforms to CGMPs and builds in a performance and patient focus that utilizes technology, statistical process control, and planning activities to ensure a reliable supply of the drugs manufactured at the facility.

  Currently, purchasers have only limited information that can be used to assess the state of quality management of any specific facility and have little information linking the drug products they buy with the facilities where they were manufactured. The lack of information does not enable the market to reward drug manufacturers with price premiums for mature quality management, back-up manufacturing capabilities, or risk-management plans, nor does it penalize manufacturers that fail to invest in modernization of manufacturing equipment and facilities to ensure a reliable supply. Thus, manufacturers are more likely to keep costs down by minimizing investments in manufacturing quality, which eventually leads to quality problems, triggering supply disruptions and shortages.

- ***Root Cause 3: Logistical and Regulatory Challenges Make It Difficult for the Market to Recover After a Disruption.*** Over the past two decades, the drug supply chain has become longer, more complex and fragmented as companies have located more production overseas (U.S. Department of Commerce 2011 and Van Den Bos 2009) and increased the use of contract manufacturers (Kuehn 2018). Although typical markets would respond to a shortage by increasing production, logistical and regulatory challenges, especially the complexity of the supply chain, can limit the ability of drug manufacturers to increase production. When companies wish to increase production, either by modifying an existing facility or building a new one, they may have to obtain approvals from many different national regulatory bodies, and/or find a new source of active pharmaceutical ingredients (APIs). If a new manufacturer wants to enter the U.S. market and start selling a drug that addresses a shortage, the manufacturer must first develop and file an application with FDA and await its approval.

RECOMMENDATIONS FOR ENDURING SOLUTIONS

Although a complex array of factors contributes to the occurrence and prolongation of drug shortages, the root causes themselves are foundational. They reflect market behavior driven by a search for cost savings in the face of a seemingly inexorable rise in health care spending. Quantifying the extent and effects of drug shortages and addressing the problem over the long term will require the active participation of private sector players – purchasers, intermediaries, and manufacturers – as well as the public sector. To address the root causes of shortages, the Task Force offers three recommendations:

RECOMMENDATION 1: CREATE A SHARED UNDERSTANDING OF THE IMPACT OF DRUG SHORTAGES AND THE CONTRACTING PRACTICES THAT MAY CONTRIBUTE TO THEM

Despite providers' widespread recognition that drug shortages profoundly affect health care delivery in the United States, there has been little private or public sector effort to collect and analyze comprehensive information to characterize shortages, quantify their effects, or closely observe the contracting practices that may be driving them. Some of the areas most needing attention are the following:

- ***Quantification of the harms of drug shortages, particularly those that lead to worsened health outcomes for patients and increased costs for health care providers***
  Previous efforts to assess the costs of drug shortages have generally been limited in scope and depth, but nevertheless suggest that the total national impact of shortages may be very large ("Identifying the Root Causes of Drug Shortages" 2018, slide 40). Given that FDA has recognized and posted on its website more than one hundred shortages at a single point in time,[9] it will require additional research to assess the full impact of shortages on patient outcomes and, more generally, on health care delivery and health care system costs. Previous estimates, at hundreds of millions of dollars annually (Kacik 2019; Kaakeh et al. 2011; "Drug Shortages Cost U.S. Care Providers" 2011), may have drastically underestimated the harms of drug shortages.

- ***Better characterization of shortages***
  Currently, neither private nor public sector stakeholders quantitatively characterize shortages in terms of their frequency, persistence, or intensity; nor do they quantify the impact of shortages on available treatments in specific therapeutic categories.[10] Having this information available to the public would help improve the understanding across all stakeholders of the impact shortages have on the Nation's health care, and support public and private strategies to prevent and mitigate shortages.

- ***Greater transparency in private sector contracting practices***
  Generic drug manufacturers have cited contracting practices as a source of business uncertainty and "race to the bottom" pricing dynamics. FDA heard from stakeholders that some contracts currently include "low-price clauses" that allow group purchasing organizations (GPOs) to unilaterally walk away from a contract if a competing manufacturer is willing to supply the same product or bundle of products for a lower price. FDA also reviewed evidence that "failure-to-supply clauses" in contracts are

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9. CDER's drug shortage list is accessible at https: www.accessdata.fda.gov/scripts/drugshortages/default.cfm; CBER's drug shortage list is accessible at https: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-current-shortages

10. FDA publishes data on current shortages on its website and makes annual reports to Congress on the number of new shortages and the number of continued shortages by year, however. See https://www.fda.gov/media/130561/download

sometimes relatively weak (Haninger et al. 2011). More systematic study of current contracting practices is needed and could support development of model contracts designed to promote reliable access to safe, effective, and affordable drugs.

RECOMMENDATION 2: CREATE A RATING SYSTEM TO INCENTIVIZE DRUG MANUFACTURERS TO INVEST IN ACHIEVING QUALITY MANAGEMENT SYSTEM MATURITY

The second root cause of drug shortages, as discussed above, is that the market does not recognize and reward mature quality management systems. This recommendation aims to rectify this failure by suggesting the development of a system to measure and rate the quality management maturity of individual manufacturing facilities based on specific objective indicators. The rating would evaluate the robustness of a manufacturing facility's quality system and reward facilities that achieve a high degree of quality system maturity.

Historically, many pharmaceutical manufacturing firms have focused their efforts on compliance with CGMPs, which include standards for material systems, equipment and facilities, production, laboratory, packaging and labeling, and a quality system. These standards, however, are foundational and set a minimum threshold that companies must achieve in order to be allowed to supply the U.S. marketplace. They do not include more advanced levels of quality management, which aim to robustly detect vulnerabilities and address them in order to prevent the occurrence of problems, nor do they establish a culture that rewards process and system improvements. As companies move from a focus on compliance with CGMPs to institutionalizing continual process and system improvement efforts, they begin to advance in quality management maturity.

A rating system could be used to inform purchasers, GPOs, and even consumers about the state of, and commitment to, the quality management maturity of the facility making the drugs they are buying. Pharmaceutical companies could, at their discretion, disclose the rating of the facilities where their drugs are manufactured. GPOs and purchasers could require disclosure of the rating in their contracts with manufacturers. This effort would introduce transparency into the market, and provide firms committed to quality management maturity with a competitive advantage, potentially enabling them to obtain sustainable prices as well as grow market share.

RECOMMENDATION 3: PROMOTE SUSTAINABLE PRIVATE SECTOR CONTRACTS

The combination of more complete information about contracting practices and greater transparency of the quality management maturity of specific manufacturing sites would enable payers, purchasers, and GPOs to consider new contracting approaches aimed at ensuring a reliable supply of medically important drugs. The objectives of these contracts should address the first two root causes discussed above by:

- ***Providing financial incentives***
  Contracts should ensure that manufacturers earn sustainable risk-adjusted returns on their investment in launching or continuing to market prescription drugs, especially older generic drugs that remain important elements of the medical armamentarium.

- ***Rewarding manufacturers for mature quality management***
  Similarly, contracts should recognize and reward manufacturing quality maturity. This could be done through several different mechanisms, such as paying higher prices for drugs manufactured at top-rated facilities, requiring a certain quality maturity rating as a condition of contracting, or guaranteeing purchase of a set volume of products from sites achieving a certain quality maturity rating.

FDA INITIATIVES TO PREVENT AND MITIGATE DRUG SHORTAGES

In addition to the recommendations above, there are several legislative proposals and planned FDA initiatives that focus primarily on enabling the Agency to help prevent supply disruptions from leading to shortages and mitigating shortages when they occur.

- ***Improved data sharing***
  A legislative proposal in the President's FY 2020 budget would expand the information required to be provided to the FDA about interruptions in manufacturing under section 506C(a) of the Federal Food, Drug, and Cosmetic Act (FD C Act) and would authorize FDA to impose penalties for failing to provide timely and adequate notification.

- ***Improved data sharing guidance***
  By the end of calendar 2019, FDA plans to publish a new draft guidance for industry that will further discuss the requirement in section 506C(a) of the FD&C Act for manufacturers to notify FDA of a permanent discontinuance in the manufacture of certain products or an interruption in the manufacture of certain products that is likely to lead to a meaningful disruption in supply of that product in the U.S. The guidance will also request that manufacturers provide additional details about the situation to ensure FDA has the specific information it needs to help prevent or mitigate shortages.

- ***Risk management plan requirement***
  A legislative proposal in the President's FY 2020 budget would authorize the Agency to require application holders of certain drugs to conduct periodic risk assessments to identify vulnerabilities in their manufacturing supply chain and develop plans to mitigate the risks of the identified vulnerabilities.

- ***Risk management plan guidance***
  By the end of calendar 2019, FDA plans to publish a new draft guidance for industry, "Risk Management Plans to Mitigate Potential for Drug Shortages." This guidance would outline a new recommendation for pharmaceutical stakeholders to develop, implement, and maintain a risk management plan for the purpose of preventing and mitigating drug shortages.

- ***Lengthened expiration dates***
  A legislative proposal in the President's FY 2020 budget would authorize FDA to require, when likely to prevent or mitigate a shortage, that an applicant evaluate, submit studies to FDA, and label a product with the longest possible expiration date (shelf life) that FDA agrees is scientifically justified. Shortages can be exacerbated if drugs must be discarded because they exceed a labeled shelf life based on unnecessarily short expiration dates.

- ***ICH Guideline Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management***
  This internationally harmonized guideline is currently being finalized. This guideline outlines ways to enhance understanding of product and process development and establish an effective pharmaceutical quality system. Incentives for adopting these guidelines include opportunities for less stringent regulatory oversight of certain post-approval manufacturing changes. Global implementation of this guideline, once finalized, could facilitate the efforts of manufacturers who wish to modernize processes and equipment, but have found the regulatory landscape to pose a financial burden.

CONCLUSION

The Task Force believes that there is no simple solution for addressing drug shortages. The root causes of shortages involve economic factors that are driven by both private and public sector decision making. The types of enduring solutions proposed here will require multi-stakeholder efforts and rethinking of business practices throughout the health care system. A fuller characterization of the true costs of shortages and more comprehensive and reliable information about their effects on patients and the health care system would be an important component, as they would better enable purchasers to factor the costs of shortages into their buying decisions. Recognizing and rewarding quality manufacturing would provide companies an incentive to achieve greater reliability in production, thus reducing the risk of supply disruptions and shortages. Finally, changes in how drugs are paid for, including potential changes in contracting, could enable generic manufacturers to charge sustainable prices for their products. Given the potential scale of impacts from drug shortages, and the fact that these impacts have continually been underestimated, it is likely that drug shortages will continue to persist absent major changes to this marketplace.

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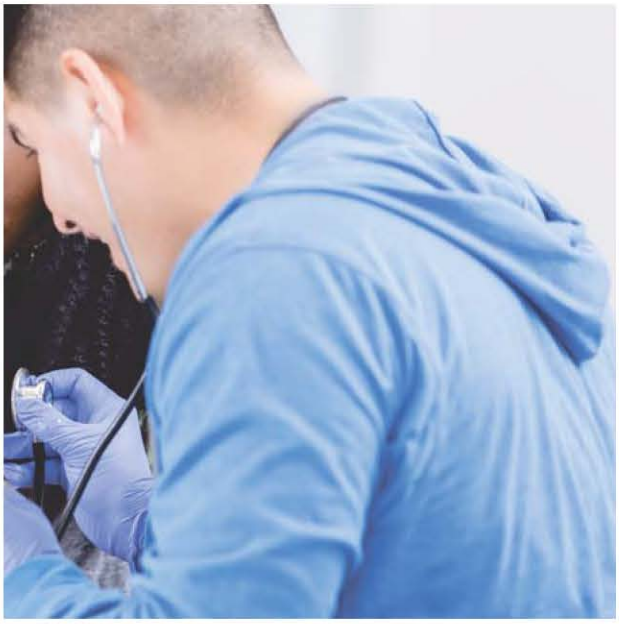
U.S. FOOD & DRUG ADMINISTRATION



Drug shortages can harm patients and impose burdens on healthcare providers.

American Hospital Association™
Advancing Health in America

Quality Advisory

AHRMM
Association for Health Care Resource & Materials Management
Advancing the Health Care Supply Chain

November 19, 2019

Ethylene Oxide Sterilization of Medical Devices

At A Glance

At Issue

In light of closures and potential closures of certain facilities that use gas ethylene oxide (EtO) to sterilize medical devices prior to their distribution and use, the Food and Drug Administration (FDA) is concerned about the future availability of medical devices and possible medical device shortages. In addition to background on the issue, this advisory highlights potential alternatives to EtO, including the advantages and disadvantages of each, as well as a resource to identify companies that sterilize instruments and equipment in the U.S.

AHA Take

Providing high-quality patient care is the top priority for America's hospitals and health systems. Our members also are committed to protecting and advancing public health. Medical devices are necessary to provide many types of services to patients, and effective sterilization is critical to significantly mitigating the risk of infection. However, the process used to sterilize those devices must fully consider and substantially eliminate any detrimental effects on public health. The AHA continues to monitor the situation and is urging government agencies and device sterilizers to develop both near- and long-range solutions that will address shortage concerns and appropriately consider and alleviate any public health implications due to the use of EtO sterilization processes.

What You Can Do

- ✓ Share this advisory with your leaders, including your chief medical officer, chief nursing officer, materials manager and others who are responsible for medical device acquisition and inventory.
- ✓ Discuss the availability of alternative sterilization processes with materials management personnel and suppliers.
- ✓ Share information related to this issue with the AHA.
- ✓ Watch for further updates.

Key Takeaways

- Ethylene oxide is used to sterilize about 50% of medical devices in the U.S.
- While some alternative methods currently exist, there are potential device incompatibility issues.
- The FDA recently held a public meeting to address potential shortages due to concerns about EtO.
- Any additional commercial sterilization facility closures could result in shortages for specific medical devices.
- Hospitals and health systems should develop a feasible contingency plan should EtO no longer be available for the sterilization of certain devices.
- The AHA will continue to update members on this issue.

Further Questions

Contact Mark Howell, senior associate director of policy, at 202-626-2317 or mhowell@aha.org.

Background

Ethylene oxide (EtO) sterilization is a chemical process consisting of four primary variables: gas concentration, humidity, temperature and time. During this process, EtO acts as an alkylating agent, effectively disrupting the DNA of microorganisms to prevent them from reproducing, ultimately resulting in sterile products suitable for medical use. Although most hospitals have gravitated away from using EtO for on-site sterilization, commercial sterilization facilities still use EtO. About 50% of all medical devices, including catheters and surgical mesh, in the U.S. are sterilized using EtO.

In December 2016, the U.S. Environmental Protection Agency (EPA) classified EtO as a carcinogen after linking it to cases of breast cancer, lymphoma and leukemia.[1] Over the course of the last year, public concerns about the emissions from sterilization facilities using EtO resulted in the permanent closure of a facility in Willowbrook, Ill., as well as temporary closures for at least two facilities in Georgia. In addition, at least one state legislature (Illinois) is considering a bill that would phase out hospital in-house use of EtO and require EtO commercial sterilization facilities operating within the state to relocate to "scarcely populated areas." Currently, shortages due to current closures are not expected, ***but*** any additional commercial sterilization facility closures could result in shortages for certain devices.

The FDA Nov. 6-7 convened an expert panel to discuss the EtO sterilization situation and to examine potential alternatives to EtO. The FDA expects the panel to make a series of recommendations on implementable next steps. Further, the FDA has initiated an innovation challenge to identify alternatives and reduce EtO emissions. In addition, the EPA is expected to release the second of two proposed rules focused on curbing the level of allowable EtO emissions produced by commercial sterilizers.

Currently, the AHA is aware of several alternative technologies that have emerged to improve sterilization time and reduce toxicity; however, it is unclear whether these alternatives can effectively sterilize the devices that currently undergo EtO sterilization. Regardless of compatibility, it is clear that substantial research and investment likely will be needed to effectively scale-up alternative options of large-scale, high-volume device sterilization.

Alternatives to EtO

As potential closures to additional sterilization facilities using EtO are possible, hospitals and health systems should identify and assess whether devices can be acquired from commercial sterilizers who do not utilize EtO.

Current alternatives to EtO include[2]*:*

[1] https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/1025_summary.pdf#nameddest=woe
[2] Content provided by Dr. Lena Shahbandar, M.D. in her article, "Alternatives to Ethylene Oxide"

- Hydrogen Peroxide and Ozone
- Vapor-Phase Hydrogen Peroxide
- Plasma (Hydrogen Peroxide)
- Peracetic Acid
- Radiation (Gamma and Electron Beam)
- Nitrogen Dioxide

The following chart describes some advantages and disadvantages of each sterilization alternative[3]:

Sterilization Method	**Advantages**	**Disadvantages**
Hydrogen peroxide vapor or plasma	• Safe for the environment, worker • Shorter processing time • No toxic residues • Used for heat and moisture sensitive items	• Potential material incompatibility with brass, zinc, copper, nickel/silver plating • Eye damage with contact • Cannot be used for cellulose like linen and paper
Peracetic acid	• Environmentally friendly byproducts • Safe to workers	• Potential material incompatibility • Used for immersible instruments only
Gamma radiation	• 60-year history • No harmful emissions • Entire volume of product is sterilized • Gas-permeable packaging is not needed	• Possible harmful changes in some plastics and tissue allografts • Question of safety of consumption of irradiated food • Requires requalification of irradiator operation annually (approximately)
E-beam	• 60-year history • No harmful emissions • Uses less product within the irradiator than gamma • Fast processing time	• Not suitable for products with challenging product geometries and localized high-density materials

[3] https://www.isms.org/Membership/Annual_Meeting/resources-lateA/

Nitrogen dioxide	• Readily penetrates packaging and complex geometry • Nontoxic/noncarcinogenic residuals • Fast processing time	• Limited compatibility questions with certain plastics • Not fully available

For hospitals and health systems looking for alternatives, this medical device directory provides a list of companies that sterilize medical supplies and equipment in the U.S. and the types of sterilization methods they employ.

Next Steps

AHA will continue to monitor the situation and provide updates as necessary. If you have further questions, please contact Mark Howell, senior associate director of policy, at mhowell@aha.org.

california **pharmacists** association

January 20, 2020

Greg Lippe
President
California Board of Pharmacy
2720 Gateway Oaks Blvd, Ste. 100
Sacramento, CA 95833

Re: Regulations on implementation of SB 159 (Wiener) on pharmacists furnishing PrEP and PEP

Dear President Lippe,

The California Pharmacists Association (CPhA) appreciates the opportunity to submit the following comments addressing proposed emergency regulations on authorizing pharmacists to independently furnish preexposure and postexposure prophylaxis (PrEP and PEP), per SB 159 (Chapter 532, 2019).

CPhA applauds the work of Licensing Chair Deborah Veale and her Board staff for the two committee hearings where stakeholders were able to provide testimony and feedback on these proposed regulations. As a co-sponsor of Senate Bill 159 (Wiener), CPhA was happy to work with Senator Scott Weiner and the other co-sponsors, Equality California, APLA Health, San Francisco AIDS Foundation, and the Los Angeles LGBT Center. We all share the common goal of increasing quality access of PrEP and PEP to patients who are at-risk of acquiring HIV. The two committee hearings were very productive and helpful in meeting this goal.

CPhA supports the committee's decision to allow the training program to encompass both PrEP and PEP instead of having two separate training programs. CPhA also supports the decision to allow for Accreditation Council of Pharmacy Education (ACPE)-approved training that meet the statutory and regulatory requirements. CPhA additionally supports the committee's decision to require that counseling for PrEP and PEP include training on how to counsel for unique populations who may be at higher risk, STI testing, and related vaccination considerations. These training requirements allow pharmacists who furnish PrEP and PEP to do so in the manner patients deserve, recognizing their individual needs and with patient safety, as always, being of utomst importance.

These proposed regulations are a great start, but CPhA feels there should be additional amendments to the language to maximize patient protection, outcomes, and access while maintaining support for pharmacists to furnish these life-saving medications. CPhA believes the committee's decision to require the training program to be a minimum of 90 minutes (an hour and a half) to be insufficient. CPhA recognizes that the intent of SB 159 is for the pharmacist to initiate a 30 to 60 day prescription for PrEP and/or initiate a 28-day prescription for PEP. However, after speaking with various experts on PrEP, the required knowledge of each medication, the patient's sexual history, intravenous drug usage, knowledge of HIV disease state, STIs, HIV testing, side effects of each medication, appropriate follow-up, referral to necessary resources or healthcare providers, and related information will require longer than 90 minutes to be appropriately trained.

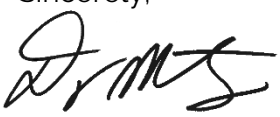
CPhA urges the Board to consider the fact that the federal Food and Drug Administration (FDA) recently approved PrEP in 2012. General knowledge about PrEP is still very low, even among pharmacists. Given that CDC's guidelines on PrEP and PEP have been updated as recently as 2017, it is vital that pharmacists have appropriate time to complete all of the necessary training per the CDC guidelines. In addition, pharmacists would need to review relevant pharmacy law and communicating the availability of financial assistance to patients per SB 159.

Based on this information, CPhA recommends that the regulations should require these programs to be a minimum of three hours to provide for enough time to appropriately train pharmacists, which would ensure standard quality of care. CPhA, in tandem with patient advocacy groups, want to ensure that pharmacists providing these vital service are able to serve their patients with the quality of care they deserve to ultimately lower the rates of HIV infection throughout the state while ensuring best practices and patient safety. Patient safety, not convenience, must be our number one priority.

CPhA would oppose any sort of specific timelines within the elements of the training being codified into law as the clinical guidelines and treatment modalities will continue to evolve. In addition, the very nature of the timelines would be inappropriate to regulate and potentially cause one or more elements of the training to be inappropriately prioritized over another.

Thank you for your consideration of our comments. Should you have any questions about these comments, please feel free to contact me at (916) 779-4519 or at dmartinez@cpha.com.

Sincerely,



Danny Martinez
Government Relations and External Affairs Manager
California Pharmacists Association.

Cc: Senator Scott Wiener
Senator Steve Glazer
Assemblymember Todd Gloria
Assemblymember Mike Gipson
Assemblymember David Chiu
Assemblymember Lorena Gonzalez

california **pharmacists** association

July 12, 2019

Victor Law, R.Ph
President, California Board of Pharmacy
2720 Gateway Oaks Blvd, Ste. 100
Sacramento, CA 95833

Dear President Law,

On behalf of the California Pharmacists Association (CPhA), I would like to submit some comments addressing the topic of the 'alternate disciplinary process' which will be considered at the Board Meeting on July 24 and 25 in Anaheim, CA.

First, CPhA would like to thank you and Enforcement Committee Chair Allen Schaad for the Board's work on addressing the creation of an alternate disciplinary process for licensees with matters being referred to the Attorney General's office for prosecution. The alternate plan that was offered during the July 10 Enforcement Committee, and being considered for adoption by the full board, is a great step in the right direction. Our members appreciate the potential opportunity to address an alleged serious disciplinary issue in a way that allows for board member involvement before going through the onerous process of the legal system. CPhA believes that this option will not only speed up disciplinary cases, but will also save the licensee and the Board time and money and provide a fairer occasion to provide mitigating evidence, if applicable. Many other states, including Arizona, Texas, Florida, Maryland, Washington and others, provide for their board members to be involved in the disciplinary process. This has statistically led to fewer cases being heard by an administrative law judge (ALJ), and quicker resolutions.

While we appreciate that California's Board seems to be moving in that direction, we'd like to offer some suggested changes to the Board's proposal that will help further get to the Board's goal of being less punitive and more collaborative and education-driven with its licensees.

Proposal to Add Section 4300.2

Notwithstanding the provisions of Government Code section 11415.60, the Executive Officer may offer, and a licensee may accept, a stipulated agreement to license discipline without and in advance of the filing of an accusation or other agency pleading, under the following conditions:

1. The board conducted an inspection or investigation as provided for in this chapter and ~~substantiated~~ alleges violations of law that warrant disciplinary action.

2. The board advised the licensee of the ~~substantiated~~ alleged violations in writing.

3. The licensee, within 15 days of being advised of the violations, notified the board in

writing of his or her willingness to conditionally waive the administrative adjudication provisions of the Administrative Procedure Act, including notice and hearing requirements, ~~and to~~ for purposes of considering a pre-filing settlement as an alternative to action taken on the basis of a pleading. The Executive Officer retains discretionary authority to extend the deadline to respond in writing beyond 15 days.

(i) The licensee may submit mitigation evidence to the Executive Officer for their consideration.

4. ~~The~~ If an agreed settlement ~~is based on the violations alleged or found~~ includes~~, and~~ any discipline ~~proposed is~~ by the Board arising from violations that are substantiated, that discipline shall be consistent with the board's Disciplinary Guidelines.A

If no pre-filing settlement between the Executive Officer and the licensee is agreed to in writing and in good faith by both parties, within 60A days of Athe licensee's notification of waiver, the Executive Officer may proceed to direct the Attorney General's Office toAprepare the appropriate pleading.

Any pre-filing settlement agreement reached between the Executive Officer and a licensee is contingent on approval by the board ~~itself~~. The board ~~itself~~ retains full authority and discretion to adopt, request modification to, or reject any such agreement. If the board requests modification to an agreement ~~is rejected by the board itself~~, the Executive Officer may offer a revised pre-filing settlement agreement consistent with any guidance from the board. ~~itself~~ If the board rejects the agreement, the Executive Officer ~~or~~ may proceed to direct the Attorney General's Office toAprepare the appropriate pleading.

We believe these changes accomplish several goals. The first goal is to clarify that unless and until a licensee has agreed to a stipulated agreement resulting in disciplinary action from the Board, or had official disciplinary action taken against them resulting from an ALJ, the licensee is only alleged to have violated the law. CPhA would not want to bias the new alternate disciplinary process by assuming a violation has occurred.

Second, CPhA would not support the waiving of any rights afforded to licensees simply because they chose this alternate route. CPhA believes that it's appropriate to waive these rights, as a condition of expediting the process of this alternate disciplinary route. However, if the licensee is unable to obtain an approved settlement, they should still be able to retain their rights under the Administrative Procedures Act when going through the traditional disciplinary process.

Third, CPhA would like to include in the statutory proposal that the licensee may submit mitigating evidence as outlined in the meeting materials of the July 10 Enforcement Committee meeting.

Fourth, CPhA would like to clarify that any settlement which results in disciplinary action by the Board will be consistent with the Board's Disciplinary Guidelines. This allows any settlement which may result in non-disciplinary action (e.g. a cite/fine, letter of admonishment, etc) to not have to be subject to the Disciplinary Guidelines.

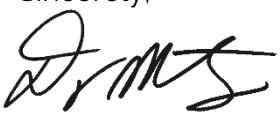
Lastly, CPhA agrees that the Board should retain full authority to accept or reject a settlement that is presented. However, it should also have the authority to request

modifications to the agreement if the Board deems necessary to do so. The current proposal only gives the Board the option to accept or reject and subsequently the Executive Officer to refer to the Attorney General. CPhA's suggested changes allow the Board to request a modification to the agreement if necessary, maintaining their involvement in the disciplinary process.

Again, CPhA is pleased to see the direction this proposal is going towards and we thank the Board and its staff for the work done on this. Should you have any questions about these suggested changes, please feel free to contact me at (916) 779-4519 or at dmartinez@cpha.com. I will also be at the Board's meeting in Anaheim to address questions or concerns in person.

Thank you for your consideration of our comments.

Sincerely,



Danny Martinez
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California Pharmacists Association.

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January 20, 2020

Gregory N. Lippe, President
California State Board of Pharmacy
2720 Gateway Oaks Blvd, Suite 100
Sacramento, CA 95833

President Lippe,

Thank you very much for the opportunity to offer input to the California State Board of Pharmacy regarding SB159's training program. I am a highly experienced HIV and PEP/PrEP consultant, physician, and educator, and strongly support SB159's goal of increasing access to PEP and PrEP, particularly in communities where utilization of these two critical HIV prevention interventions remains limited and/or stigmatized.

In my experience, I believe the minimum number of training hours necessary for pharmacists to furnish PEP and PrEP within the parameters of SB159 should be no less than 2-3 hours, in order to ensure all requirements are adequately met. With regard to overall structure/content, training should include details on the relevant regulatory aspects of SB159 and its implementation; clinically appropriate use of PEP and PrEP as informed by current guidelines and established best practices (this includes information on indicated lab testing and interpretation of testing results); guidance on appropriate patient counseling; and available patient resources (e.g. medication assistance programs) as well as resources for pharmacists and treating clinicians (e.g. other PEP/PrEP-focused education and training opportunities, local AIDS Education and Training Centers programming).

Increased engagement with—and support for—pharmacists, especially those in communities that have not placed a strong focus on HIV prevention and outreach, will be the cornerstone to SB159's success. As you are undoubtedly aware, the ideal training program will be able to effectively strike a balance between sufficiently engaging interested pharmacists to commit time/effort to such training while ensuring patient and provider safeguards [as relevant to SB159] are met. Thank you for your commitment to ensure the successful development of this training program.

Kindly,

Carolyn Chu, MD, MSc, FAAFP, AAHIVS
Associate Professor, Department of Family & Community Medicine, UCSF
Co-Chair, CA/HI Chapter Steering Committee, American Academy of HIV Medicine
Clinical Director, National Clinician Consultation Center (National PEPline | PrEPline)

January 21, 2020

Greg Lippe
President
California Board of Pharmacy
2720 Gateway Oaks Blvd, Ste. 100
Sacramento, CA 95833

Dear President Lippe,

I am writing this letter to provide input to the Board of Pharmacy regarding the SB159 training requirement. I've worked very closely with the co-authors of the bill. I have been an HIV community pharmacist for over 17 years and I have implemented a community pharmacy PrEP (pre exposure prophylaxis) program under a collaborative practice agreement with the San Francisco Department of Health. I am also the residency director of our ASHP- accredited Community PGY1 program and serve as voluntary faculty at both UCSF and Touro Schools of Pharmacy. I have trained pharmacists and residents in PrEP as well as provided talks on PrEP. Currently I am completing the development of a 2- hour live presentation on PrEP for community pharmacists for the 2020 APHA annual meeting. I am also in the process of creating several additional PrEP training programs and papers. I, along with Betty Dong, HIV Emeritus Professor at UCSF School of Pharmacy, Robert M Grant, iPrEX lead investigator who was responsible for FDA approval for PrEP and who testified on the safety of pharmacists providing PrEP for SB159 have a paper coming out soon. The paper details recommended training for community pharmacists providing PrEP.

Based on my experience I believe the minimum amount of hours necessary for pharmacists to initiate PrEP and PEP (post exposure prophylaxis) should be no less than 3 hours. This number is based on the following reasons, including my experience as well as discussions with other colleagues of mine who provide education on PrEP.

Community pharmacists should receive continuing education on PrEP, STIs, laboratory interpretation of tests associated with PrEP and counseling. Community pharmacists are traditionally not accustomed to reviewing and interpreting laboratory values and should receive additional training on the laboratory tests associated with PrEP initiation as well as counseling on risk reduction with associated infections related to PrEP; including HIV, hepatitis C (HCV), hepatitis B, sexually transmitted infections (STIs) with an emphasis on gonorrhea, chlamydia and syphilis, but also herpes simplex virus (HSV) and human papilloma virus (HPV). All pharmacists must be prepared to competently counsel patients on HIV transmission, risk reduction, sexually transmitted infections, including identifying key symptoms of STIs, when to refer and recommendations for frequent testing. The training should also include how to provide culturally appropriate counseling and risk reduction in vulnerable populations,

including trans persons, gay, bisexual, men who have sex with men, minority communities, sex workers and persons who inject drugs.

Currently, there are PrEP CEs available for pharmacists which are knowledge based and describe the CDC guidelines. However, I do not believe they are adequate for community pharmacists initiating PrEP and PEP. It is common for these pharmacist PrEP CEs to run in the range of 1-1.5 CE hours. Additionally, pharmacist CE's on sexually transmitted infections (STIs) are at least 1 CE hour. Based on my training and the currently available CEs, I believe it is reasonable to include an additional hour for a minimum of 3 hours to include the above topics. I urge the Board consider the minimum training requirements necessary in order for community pharmacists to competently provide PrEP and PEP initiation while ensuring patient safety. I believe community pharmacists can do a number of combinations in order to meet the requirements while not being overly burdensome. For example, pharmacists can complete pre reading or an online 1- hour PrEP CE, in combination with additional CEs (on STIs, laboratory tests and counseling) in order to supplement and meet the minimum requirements. It is very important that community pharmacists have the necessary training in order to successfully implement SB159 and help end the HIV epidemic.

Sincerely,

Maria Lopez, PharmD, AAHIVP

Jessica Langley
National Healthcareer Association
11161 Overbrook Road
Leawood, KS 66211

January 23, 2020

By Overnight Delivery and Email
California State Board of Pharmacy Licensing Committee
C/O Debbie Veale, Chairperson
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

NHANOW.COM

RE: Discussion and Consideration of Board's Proposal to Establish New Licensing Programs Related to Advanced Pharmacy Technician Requirements and Functions (Proposed BCP 4038.5, 4115.6-4115.7 and 4211, together referred to as "Proposed Advanced Tech Licensing")

Dear Chairperson Veale and the California Board of Pharmacy,

We, at NHA, support the Board's continued efforts to establish and revisit Pharmacy Technician rules pertaining to the advancement of the technician profession. As you may be aware, NHA has partnered with the California Pharmacists Association to service and support the technician workforce by providing quality training resources, exam preparation materials and accredited certification exams. We all share in the goals and desires to advance the pharmacy technician profession and empower these individuals with the appropriate resources to work to the top of their license and to have a successful career, all while benefiting the health and wellness of California consumers.

We understand that the Committee is discussing Proposed Advanced Tech Licensing at an upcoming meeting in January, and NHA would like to provide feedback on the basic tenets of the proposal, as well as be engaged in ongoing Committee discussions. We generally support this initiative but are concerned with some aspects of the Licensing Requirement found in Proposed BCP 4211. Our recommendations to improve Proposed BCP 4211 are as follows:

> **Proposed BCP 4211 (Licensing Requirement)**
> The board may issue an advanced pharmacy technician license to an individual who meets all the following requirements:
>
> (a) (1) Holds an active pharmacy technician license issued pursuant to this chapter that is in good standing <u>through the first renewal cycle, which requires the completion of continuing education credits.</u>
> (2) Has obtained ~~2,050~~ a minimum of 3,000 hours of experience performing the duties of a licensed pharmacy technician or pharmacist intern in a pharmacy.

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Leawood, Kansas 66211
P 913-721-5632

(3) documented training or competency in the applicable advance practice skill(s) being performed.
(34) Satisfies at least one of the following requirements:

(A) Possesses a certification issued by a pharmacy technician certifying program as defined in Section 4202(a)(4).
(B) Has obtained a minimum of an associate degree in a pharmacy-focused discipline.
~~technology~~.
~~(C) Has obtained a bachelor's degree~~

(b) A license issued pursuant to this section shall be valid for two years.

NHANOW.COM

We believe that awarding an advanced pharmacy technician license after only one year of practice, as proposed in 4211(a)(1), will promote candidates who have a limited breadth of experience and who have not proven a commitment to the profession. In many practice settings, a pharmacy technician's experience after only one year of practice can be very narrow, sometimes even single task-oriented. There may be little opportunity to assess the ability of such pharmacy technicians to take on additional responsibility, possibly creating a situation where a technician may receive an advanced license from the State well before the supervising pharmacist has ascertained the technician's readiness for an expanded scope of practice. The willingness to be nationally certified, complete continuing education, and renew an initial license also serves as an indicator of dedication to the profession and a level of maturity that is aligned with an expanded scope of practice.

We have added section (a)(3) because, given that an advanced license is transportable from one pharmacy to another, we believe that evidence of training or competency in the advanced skills should be presented to the State at the time of licensure. This will give subsequent employing pharmacies confidence that a presenter of the license has obtained the underlying training for the increased scope of practice.

We also suggest deleting subsection (3)(C). First, unlike the requirement of pharmacy technician certification (subsection (3)(A), now (4) (A)) or degreed education in pharmacy technology (subsection (3)(B), now (4)(B)), a general bachelor's degree does not demonstrate the knowledge or competency needed to support an advance pharmacy technician license. A bachelor's degree in fine arts, computer sciences or languages bears no relationship to pharmacy technician practice but would satisfy the requirement of proposed subsection 3(C). There is no reason why a practicing pharmacy technician who had, at some prior time in his/her life, obtained an unrelated degree, be excused from obtaining certification, which demonstrates that the technician has obtained a base level understanding of pharmacy technician practice. Second, subsection (3)(B) (now (4)(B)) is written broadly enough to include post-associate pharmacy education, negating a need to address advanced pharmacy degrees via proposed subsection (3)(C).

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We thank you for the opportunity to share our feedback and look forward to the discussion at the upcoming meeting.

Sincerely,

Jessica Langley
Executive Director of Education and Provider Markets
National Healthcareer Association

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P 913-721-5632

CSHP | CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
Partners in Medication Management

January 24, 2020

Greg N. Lippe, President
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite100
Sacramento California, 95833
FAX (916) 574-8618

RE: Legislative Committee Proposal to Establish an Advanced Pharmacy Technician Licensee Category

Dear Mr. Lippe:

The California Society of Health-System Pharmacists (CSHP) is respectfully opposed to legislation, as proposed by the Board of Pharmacy Legislative Committee, to create a new licensee category of Advanced Pharmacy Technician. CSHP has and continues to support the advancement of both Pharmacist and Pharmacy Technician practice to meet the evolving healthcare needs of the 21st century. To that end we appreciate the Licensing Committee's efforts to act upon the discussions that have surrounded pharmacy technician practice over the past many years.

While CSHP supports the intention of the Committee's proposal to be responsive to many earlier discussions regarding pharmacy technicians' authorized functions and qualifications that support pharmacist-provided services, we are concerned with the language of the Committee's proposal and its implications for pharmacy practice settings. The proposed legislative language for establishment of an Advance Pharmacy Technician, contains concepts which don't align with current practice and may generate unanticipated outcomes such as restrictions on the use of pharmacist supportive personnel.

We believe that in order to yield the best results for patients, pharmacists, pharmacy technicians and employers a robust stakeholder process that includes a broad array of representatives is imperative. This will allow all affected parties to be at the table and do an in-depth analysis of the details that must be addressed for an expansion policy change to ensure there is alignment with current practice and

recently passed and proposed California legislation (e.g., pharmacy technician ratios and remote pharmacy services).

CSHP is eager to offer our assistance in convening a forum for interested parties to discuss issues and implications for a holistic approach to advancing pharmacy technician practice in alignment with pharmacist delivered care provided in all practice settings. With the input of interested and impacted stakeholders, CSHP stands ready to sponsor legislation to secure the recommendations of the pharmacy practice forum.

Founded in 1962, CSHP represents thousands of pharmacy professionals across California who serve patients and the public through promotion of wellness, patient safety and the optimal use of medications. CSHP members practice in all types of pharmacy settings -- including but not limited to, hospitals, integrated health systems, clinics, ambulatory care settings, long term care, retail, community and home healthcare.

Respectfully,

Loriann De Martini, Pharm.D., BCGP
Chief Executive Officer,
California Society of Health-System Pharmacists

Executive Director,
California Society of Health-System Pharmacists Foundation

cc: Deborah Veale, Licensing Committee Chairperson
Anne Sodergren, Interim Executive Officer

CHA MEDICATION SAFETY COMMITTEE
2020 ROSTER

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Medication Safety Committee
Hospital Representation

BY COUNTY

As of February 25, 2020

Denotes number of hospitals/health systems represented within that county.

Contact	Position Type	Represented Organization	County (Represented Org
Candace Fong, Pharm.D	Chair	Dignity Health	San Francisco
Jeanette Hanni, R.Ph, MPA, FCSHP	Chair	Sutter Health	Sacramento
Amy Gutierrez, PharmD	Member	Kaiser Permanente	Alameda
Deepak Sisodiya, PharmD, MHA	Member	Stanford Health Care	Santa Clara
Diana Schultz, RPh, MHSA	Member	Sharp HealthCare	San Diego
Doug O'Brien, Pharm.D	Member	Kaiser Foundation Hospitals	Sacramento
Eddie W. Avedikian, PharmD	Member	Providence Holy Cross Medical Center	Los Angeles
Kathy Ghomeshi, Pharm.D, MBA, BCPS, CPPS	Member	UCSF Medical Center	San Francisco
Kevin Dorsey Tyler, MD, PhD	Member	Enloe Medical Center - Esplanade Campus	Butte
Lori Nolan-Mullenhour, MSN, RN, NE-BC, CEN	Member	Providence Little Company of Mary Medical Center Torrance	Los Angeles
Nasim Karmali, RPh	Member	Kaiser Permanente Redwood City Medical Center	San Mateo
Reynaldo Rosario, MSN, RN-BC, CPHQ	Member	Santa Clara Valley Medical Center	Santa Clara
Richard B. Rabens, MD, MPH, FAAP	Member	Kaiser Permanente	Alameda
Rita Shane, Pharm.D, FASHP, FCSHP	Member	Cedars-Sinai Medical Center	Los Angeles
Sarah Stephens, Pharm. D, BCPS, CPPS	Member	Kaweah Delta Health Care District	Tulare
Anne Sodergren	Ex-officio	California Board of Pharmacy	
Art Woo, Pharm.D	Ex-officio	California Department of Public Health	
Cari Lee, Pharm.D	Ex-officio	California Department of Public Health	
John Christensen, Pharm.D	Ex-officio	California Department of Public Health	
Loriann DeMartini, Pharm.D	Ex-officio	California Society of Health System Pharmacists	
Patti Owens	Ex-officio	California Association of Health Facilities	
Randy Kajioka, Pharm.D	Ex-officio	California Correctional Health Care Systems	
Lisa Gunther Lum	Ex-officio	California Society of Health System Pharmacists	
Keith Yoshizuika, PharmD, MBA, JD, FCSHP	Ex-officio	California Society of Health System Pharmacists	

GUIDELINES FOR THE
CALIFORNIA HOSPITAL ASSOCIATION
MEDICATION SAFETY COMMITTEE

I. NAME

The name of this committee shall be the Medication Safety Committee.

II. MISSION

The mission of the Medication Safety Committee is to provide leadership within the health care community to promote the highest standards related to the safe and effective use of medications.

III. PURPOSE

The purpose of the Medication Safety Committee is to provide a forum for diverse multi-disciplinary health care organizations, which includes health care delivery organizations, patient safety organizations, discipline specific professional associations/organizations and regulatory agencies, to promote safe medication practices in the state of California. The Committee will focus on acting as a source of medication safety expertise, providing a venue for the coordination of medication safety activities and making recommendations related to medication safety legislation and regulations.

IV. COMMITTEE

The Committee (the "Committee") shall consist of a minimum of 16 representatives and not more than 35 representatives from hospital members and the following related organizations:

California Department of Public Health California
Society of Health System Pharmacists California
Board of Pharmacy
Centers for Medi-Care and Medi-Caid Services
Collaborative Alliance for Nursing Outcomes
Association of California Nurse Leaders California
Medical Association
California HQI and CHPSO
Risk Management Association
Representatives from the following CHA committees/centers:
Center for Behavioral Health
- Rural Health Center
- Quality Committee
- Joint Committee on Accreditation and Licensing Center
- for Hospital Medical Executives EMS/Trauma
- Committee
- Hospital Based Clinics Committee
- Center for Post Acute Care
- Governance

A. MEMBERSHIP

1. Membership on the Committee shall be based upon membership in CHA, or organizations that have a direct relationship to the purpose and mission of the Committee. CHA members will be hospital members. Non-hospital members are ex-officio members and can only be appointed to the Committee at the discretion of the CHA staff liaison.
2. The CHA Committee members shall consist of various representatives from large hospital systems, public institutions, private facilities, free-standing facilities, small and rural facilities, university/teaching facilities and specialty facilities. A member may fulfill more than one required membership position.
3. Hospital members are appointed by CHA Staff per recommendation of hospital Committee members and per hospital and non-hospital membership requirements listed above.
4. Guidelines for membership – these guidelines should be used when selecting potential new members for the Committee:
   a) Demonstrated experience in medication safety and understanding of regulatory environment based on current or recent job responsibilities
   b) Contributions to medication safety at the organizational and/or professional level
   c) Practice experience related to medication safety and regulatory compliance: at least 3 years (preferred).
5. Term:
   a) Terms of office shall be based on member participation and desire to remain active on the Committee. The CHA staff liaison will perform an annual review of member attendance, participation and desire to remain active on the committee.
   b) Chairs and Co-Chair positions will be filled by hospital members only and selected by the CHA staff liaison per recommendation of the present chair, co-chairs and by other members of the Committee. They will be selected based on their leadership and desire to fill the position.

B. MEMBER RESPONSIBILITIES

1. Provide hospital-industry leadership to the Committee and CHA Board of Trustees.
2. Identify issues and develop possible solutions and best practices to improve the safety of the medication use process.
3. Work cooperatively with key stakeholders to develop creative solutions.
4. Provide communication to member hospitals regarding medication safety issues.
5. Maintain/increased awareness of the legislative and regulatory environment with regard to medication safety issues.

C. COMMITTEE MEETINGS

1. Meetings of the Committee shall be held quarterly in person.
2. To maintain continuity, substitution of members should be discussed with the staff liaison and co-chairs on an individual basis.
3. Three consecutive unexcused absences by a Committee member will initiate a review by the co-chairs and CHA staff liaison for determination of the Committee member's continued service on the Committee.
4. Special meetings may be scheduled by the co-chair, majority vote, or CHA staff liaison.

D. VOTING

1. Voting rights shall be limited to members of the Committee, and each member present shall have one vote. Voting by proxy is not acceptable.
2. All matters requiring a vote of the Committee must be passed by a majority of a quorum of the Committee members present at a duly called meeting or telephone conference call.

E. QUORUM

Except as set forth herein, a quorum shall consist of a majority of members present or not less than eight.

F. MINUTES

Minutes of the Committee shall be recorded at each meeting, disseminated to the membership, and approved as disseminated or as corrected at the next meeting of the Committee.

V. OFFICERS

The officers of the Committee shall be the Committee chair, co-chair and CHA staff liaison.

A. SUB-COMMITTEES

1. Task forces of the Committee may be formed at the discretion of the Committee chairs and members and CHA staff liaison for the purpose of conducting activities specific to a special topic or goal.

VI. GENERAL PROVISIONS

Goals, and objectives, shall be developed annually by the Committee with approval by the CHA staff liaison. Quarterly updates and progress reports shall be completed by the Committee and CHA staff.

Staff leadership at the state level shall be provided by CHA with local staff leadership provided by Hospital Council, the Hospital Association of Southern California, and the Hospital Association of San Diego and Imperial Counties. The primary office and public policy development and advocacy staff of the Committee shall be located within the CHA office.

The Committee staff liaison shall be an employee of CHA.

VII. AMENDMENTS

These Guidelines may be amended by a majority vote of the members of the Committee at any regular meeting of the Committee and with approval by CHA.

VIII. LEGAL LIMITATIONS

Any portion of these Guidelines which may be in conflict with any state or federal statute or regulations shall be declared null and void as of the date of such determination.

Information provided in meetings is not to be sold or misused.

IX. CONFIDENTIALITY FOR MEMBERS

Many items discussed are confidential in nature, and confidentiality must be maintained. All Committee communications are considered privileged and confidential, except as noted.

X. CONFLICT OF INTEREST

Any member of the Committee who shall address the Committee in other than a volunteer relationship excluding CHA staff and who shall engage with the Committee in a business activity of any nature, as a result of which such party shall profit either directly or indirectly, shall fully disclose any such financial benefit expected to CHA staff for approval prior to contracting with the Committee and shall further refrain, if a member of the Committee, from any vote in which such issue is involved.

MEDICATION SAFETY COMMITTEE
MEETING MINUTES
October 17, 2019 / 12:00 – 2:00pm

Disneyland Hotel, Anaheim, CA

Members Participating: **Eddie Avedikian, Loriann DeMartini, Candace Fong, Kathy Ghomeshi, Jeannette Hanni, Doug O'Brien, Rita Shane, Diana Schultz, Sarah Stephens**

CHA Staff: **BJ Bartleson, Barb Roth**

I. **CALL TO ORDER/INTRODUCTIONS (Hanni/Fong)**
The committee meeting was called to order by chair Ms. Fong at 12:15 pm.

II. OLD BUSINESS

A. Sterile Compounding Updates and Next Steps (Bartleson)
OSHPD, BoP and CDPH will be participating in a CHA webinar on November 12 from 1-3 pm. There is confusion in the hospital pharmacies about the regulations.

- *ACTION: CHA to request a public statement from regulators prior to the webinar.*

B. USP 800 Hazardous Drugs – Handling in Healthcare Settings (Bartleson)
Does CHA need to do something to address this, perhaps a webinar?

- *ACTION*:

C. Inventory Reconciliation and Automatic Dispensing Units (Fong)
BoP advised that this would be going to their legal counsel to see how it should be interpreted. Hospitals are still getting cited.

- *ACTION: CHA to follow up with BoP.*

D. Biosimilars (Bartleson)
Insurance providers requiring hospitals to provide specific drugs (biosimilars) will cost hospitals and patients more if they are not able to stock/provide the specific. (Cedars-Sinai and UC Hospitals)

- *ACTION: Ms. Bartleson to check in with the CHA DC and Legislative/Advocacy Teams.*

E. Medication Safety Tool Review (Bartleson)
Information provided from CHA Communication Department regarding views to the Medication Safety Tool on the CHA website. Views are down to 236 views Jan-Oct 2019 vs. 527 views Jan-Oct 2018.

- *ACTION: Recommendation to keep the tools.*

III. NEW BUSINESS

A. CSHP Presentation (Bartleson)
Ms. Hanni and Ms. Fong will be presenting information about the Medication Safety Committee during a session at the CSHP conference on Friday, Oct. 18.

- *ACTION: Information only.*

B. Title 22 Pharmacy Pre-Regulation All Facilities Letter (AFL 19-27) For Pharmaceutical Regulations (Bartleson)

- *ACTION: Ms. Bartleson to check for email from Loriann with revisions.*

IV. LEGISLATION

A. All Pharmacy Bills (Bartleson)

B. Signed Pharmacy Bills (Bartleson)
SB 159: Governor Newsom approved a HIF: preexposure and postexposure prophylaxis bill.

- *ACTION: Ms. Bartleson will continue to follow and keep committee members informed*

C. Bridge Program
Challenges with BoP regulations regarding dispensing Naloxone.

- *ACTION: Ms. Fong to provide barrier regulations to Ms. Bartleson.*

V. STANDING REPORTS

A. Board of Pharmacy (BoP)

B. California Department of Public Health (CDPH)

C. California Society of Health System Pharmacists (CSHP)

D. California Association of Health Facilities

VI. INFORMATION

A. Acetaminophen: What it is, How It's Used, and the Importance of Access – Prop 65 Briefing Packet
B. Minutes – July 17, 2019 Meeting – **deemed approved by email.**
C. Member Roster/Map/Breakdown
D. Committee Guidelines

VII. NEXT MEETING
TBD

VIII. ADJOURNMENT
Having no further business, the committee adjourned at 1: pm.