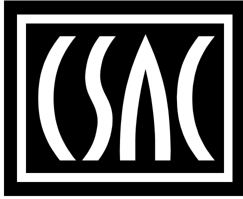

Health and Human Services Policy Committee

Wednesday, March 25 ▪ 3:00 – 4:00 p.m.
Via Conference Call
Dial In: (800) 867-2581 ▪ Passcode: 7500559#

Supervisor Ken Yeager, Santa Clara County, Chair
Supervisor Hub Walsh, Merced County, Vice Chair

3:00 p.m.	**I.**	**Welcome and Introductions** *Supervisor Ken Yeager, Santa Clara County*
3:05 – 3:20	**II.**	**Budget and Legislative Update** *Farrah McDaid Ting, Legislative Representative* *Michelle Gibbons, Legislative Analyst*
3:20 –3:40	**III.**	**1115 Medicaid Waiver Update** *Kelly Brooks-Lindsey, Hurst Brooks Espinosa Advocacy*
3:40 – 4:00	**IV.**	**Review of Tobacco-Related Legislation**
4:00	**V.**	**Adjournment**

NOTES:
Please note new passcode digits: 7500559#
For those who wish to attend the meeting, it will be held in CSAC's Peterson Conference Room (1st floor, 1100 K Street, Sacramento).
The conference call number is noted above for those who wish to call in.

Conference Call Etiquette

1. Place your line on **mute** at all times until you wish to participate in the conversation.
2. **DO NOT PLACE THE LINE ON HOLD.**
3. Please identify yourself when speaking.

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March 23, 2015

To: Supervisor Ken Yeager, Chair, CSAC Health & Human Services Policy Committee
Supervisor Hub Walsh, Vice Chair, CSAC Health & Human Services Policy Committee
Members, CSAC Health & Human Services Policy Committee

From: Farrah McDaid Ting, Legislative Representative
Michelle Gibbons, Legislative Analyst

Re: Federal Medicaid Waiver Renewal: Medi-Cal 2020 Draft Paper

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The Department of Health Care Services (DHCS) released their Medicaid Section 1115 concept paper for the Medi-Cal 2020 Waiver and recently convened a webinar on the concept paper for stakeholders.

CSAC has contracted with Kelly Brooks-Lindsey to represent CSAC on the many facets concerning the waiver renewal. In the attached memo, Mrs. Brooks-Lindsey provides an overview of DHCS' concept paper and details on the webinar.

For more information about the state's proposal, please visit the Department of Health Care Service's Section 1115 Waiver Renewal page at:
http://www.dhcs.ca.gov/provgovpart/Pages/WaiverRenewal.aspx

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HURST+BROOKS+ESPINOSA

March 20, 2015

TO: Matt Cate, Executive Director, CSAC

FROM: Kelly Brooks-Lindsey, Partner, Hurst Brooks Espinosa, LLC

Re: Medicaid Section 1115 Waiver Renewal: Medi-Cal 2020 Draft Paper

The Department of Health Care Services (DHCS) unveiled its draft Medicaid Section 1115 Waiver concept paper on March 16, 2015, followed by a webinar on March 18. The concept paper includes a number of proposals previously discussed with stakeholders. DHCS intends to submit a final proposal to the Centers for Medicare and Medicaid Services (CMS) on March 27, 2015. They are currently soliciting feedback from stakeholders on the draft concept paper. Counties can submit comments to WaiverRenewal@dhcs.ca.gov. Additionally, DHCS is encouraging stakeholders to submit letters of support to CMS.

This memorandum provides an overview of DHCS's concept paper and additional detail provided on the webinar.

BACKGROUND

California's "Bridge to Reform" Medicaid Section 1115 Waiver expires on October 31, 2015. The current waiver provides approximately $10 billion to California over its five-year life, with $2 billion directly benefiting the state General Fund. The Brown Administration, under the leadership of DHCS, is moving forward to renew the waiver.

California's waiver renewal, which is dubbed Medi-Cal 2020, represents the state's vision for continued transformation of the Medi-Cal program's delivery and payment systems. California is focused on critical aspects of health reform, including expanding access, improving quality and outcomes, and controlling the cost of care. DHCS believes the waiver proposal is also a framework for ensuring ongoing support for California's safety net and ensuring the long-term viability of Medi-Cal and the Medicaid expansion.

Medi-Cal 2020 makes the case for a waiver renewal worth $15 to $20 billion in federal funds for the next five years.

The paper emphasizes California's trailblazing in managed care enrollment – 80 percent, or over 9 million individuals, are currently enrolled into Medi-Cal managed care plans. The paper also heavily emphasizes continued integration of primary and behavioral health care as an important component of the next phase of the waiver demonstration.

The paper details three key strategies for achieving the vision of Medi-Cal 2020:

- **Delivery System Transformation and Alignment Programs.** DHCS is proposing to "reinvent thinking on how to promote quality, improve health outcomes, expand access and promote cost efficiency" by creating six cross-cutting programs that DHCS believes will advance delivery system transformation:

    1) Managed Care Systems Transformation & Improvement Program
    2) Fee-for-Service Transformation & Improvement Program
    3) Public Safety Net System Transformation & Improvement Program
    4) Workforce Development Program
    5) Increased Access to Housing and Supportive Services
    6) Whole Person Care Pilots

- **Public Safety Net Global Payment for the Remaining Uninsured.** Transforming California's public safety net for the remaining uninsured by unifying the Disproportionate Share Hospital (DSH) and Safety Net Care Pool (SNCP) funding streams into a global payment system.

- **Shared Savings.** California is proposing to test a new investment strategy with the federal government by initiating a Federal-state shared savings model.

Each of these waiver elements are discussed in greater detail on the following pages.

CSAC PRIORITIES

There are a number of major priorities for counties heading into the waiver renewal discussions, including ensuring that the next waiver includes the same level of funding for public hospitals and counties. Additionally, it is important that another Medicaid waiver include a Delivery System Reform Incentive Program (DSRIP) successor that will allow public hospitals and health systems to continue the important transformation work, continue to improve outcomes, and increase efficiencies. There are also important opportunities for improving care coordination – through a county-based whole person care pilot and in better integrating primary care and behavioral health services.

DHCS's draft concept paper, as presented on March 16, addresses the counties' priorities. Additionally, the paper introduces a new concept transforming California's public safety net for the remaining uninsured by created a global payment system. Individual payments would allow each hospital system more certainty about its budget and how much federal funds would be available. The global payments

offer a unique opportunity for California to serve as an incubator in testing new payment methods for delivering care to the uninsured and in transforming care away from high cost settings – like emergency rooms – toward primary care.

Additionally, counties should note that the waiver document is very cross-cutting and impacts a number of county services – including county health and hospital systems, public health, mental health, substance use disorder treatment, social services, housing, homeless services, veterans' services, probation and public safety. DHCS's vision for Medi-Cal 2020 includes breaking down silos across public systems, providers and health plans to improve care for Medi-Cal members. It is clear that to achieve the Triple Aim, health plans, providers and public systems – health, behavioral health, social services, and public safety – will need to forge new and lasting relationships focused on outcomes.

FINANCING

The current waiver has provided approximately $10 billion in federal funds over the five-year life of the waiver. The Medi-Cal 2020 concept paper includes details to support $17 billion in federal funds for a five-year waiver renewal. DHCS is proposing to continue a number of elements from the current budget neutrality calculation into the 2015 waiver renewal, which assists in California's case for approximately $7 billion in additional federal funds.

Budget Neutrality Background. Part of the budget neutrality calculation requires states to calculate their costs without the waiver and then to update those costs with the waiver. The difference between the "without" waiver and "with" waiver costs is the basis for budget neutrality. States use the budget neutrality calculation to inform how they approach CMS in asking for additional federal funds. See page 35 of the concept paper and Appendix D for additional detail on budget neutrality.

The Medi-Cal 2020 concept paper details that the existing Medicaid Section 1115 waiver authorities and programs that would continue through 2020 include the Coordinated Care Initiative, the Community Based Adult Services (CBAS) waiver, the managed care program, Indian Health Services uncompensated care, Designated State Health Programs, the pending Drug Medi-Cal Organized Delivery System waiver, and the provision of full scope benefits for pregnant women with incomes between 109-138% of the federal poverty level.

California's current waiver uses fee-for-service (FFS) costs in its budget neutrality calculation. The movement of seniors and persons with disabilities into Medi-Cal Managed Care occurred in the existing waiver and the geographic managed care expansion. In the 2010 waiver, DHCS's budget neutrality calculation included a comparison of per member per month costs of Medi-Cal beneficiaries in FFS and in Medi-Cal managed care.

DHCS is proposing to continue to calculate budget neutrality by using a comparison of FFS costs with managed care costs. DHCS has acknowledged that CMS will likely raise questions with the continued assumption of FFS for the "without" waiver calculation. Counties should anticipate that this will likely be a negotiation point between the state and federal governments.

DHCS released some funding detail on the March 18 webinar not included in the Medi-Cal 2020 concept paper. Additional funding details include:

- **Global Payments for the Uninsured:** $6.2 billion in federal funds for five years to transform existing DSH and SNCP payments into public safety net global payments ($12.4 billion total funds) for the remaining uninsured. The current waiver includes $236 million in SNCP funds in the final 16-months of the waiver.

  Please recall that the Administration is proposing to combine SNCP and Disproportionate Share Hospital (DSH) funds into global payments for the remaining uninsured. Currently DSH and SNCP are only available for designated public hospitals; the global payments proposal funding source would only be available for designated public hospitals in the 2015 waiver.

  The current waiver does not include DSH payments in the budget neutrality calculation. The Administration is assuming that the federal DSH allotment that California would otherwise receive will be part of the global payments. It is anticipated DSH payments will be approximately $1.1 billion in 2016. DSH payments will decline over the life of the waiver due to cuts slated to occur at the federal level. DSH payments are included in the 2015 waiver budget neutrality calculation on both the "without" and "with" waiver.

- **State designated health programs:** $400 million in federal funds each year for five years ($2 billion total) for state designated health programs. The current waiver contains $2 billion for state designated health programs. As part of California's 2010 waiver, CMS approved the following designated state health programs as eligible for federal match:

  - ✓ California Children's Services (CCS)
  - ✓ Genetically Handicapped Persons Program (GHPP)
  - ✓ Medically Indigent Adult Long Term Care (MIALTC)
  - ✓ Breast and Cervical Cancer Treatment Program
  - ✓ AIDS Drug Assistance Program
  - ✓ Expanded Access to Primary Care (EAPC)
  - ✓ County Mental Health Services Program
  - ✓ Department of Developmental Services
  - ✓ Prostate Cancer Treatment Program
  - ✓ Cancer Detection Programs; Every Woman Counts
  - ✓ County Medical Services Program (for the period November 1, 2010 through December 31, 2011)
  - ✓ Office of Statewide Health Planning and Development:
    - Song Brown HealthCare Workforce Training Program
    - Steven M. Thompson Physician Corp Loan Payment Program
    - Mental Health Loan Assumption Program

- **Public Safety Net System Transformation & Improvement Program:** $800 million in federal funds each year for five years ($4 billion total federal funds) for a Delivery System Reform

Incentive Program (DSRIP) successor that DHCS is calling Public Safety Net System Transformation and Improvement Program. The current waiver contains approximately $3.3 billion for DSRIP. DHCS is proposing to include non-designated hospitals, or district hospitals, in the Public Safety Net System Transformation and Improvement Program in the 2015 waiver. Currently DSRIP is available only to designated public hospitals.

- **Delivery system transformation and alignment payments:** $2 billion each year for five years in federal funds ($10 billion total) for the delivery system changes for five cross-cutting programs that DHCS believes will advance delivery system transformation: 1) Managed Care Systems Transformation & Improvement Program; 2) Fee-for-Service Transformation & Improvement Program; 3) Workforce Development Program; 4) Increased Access to Housing and Supportive Services; and 5) Whole Person Care Pilots. DHCS has not provided detail regarding how the $2 billion would be allocated among the five cross-cutting programs.

The following chart details the elements of the waiver proposal and the proposed federal funding and total funding levels over the five years. The figures in the chart assume that the federal government agrees to California's shared savings proposal.

MEDI-CAL 2020 PROGRAM FUNDING – FEDERAL FUNDS & TOTAL FUNDS

	5-Year Total Federal Funds	**5-Year Total All Funds**
Global Payments for the Uninsured (merging of DSH and SNCP)	$6.2 billion Funds decline over the 5 years – starting at $1.4 billion in FY 16-17 and declining to $1.25 billion in FY 19-20.	$12.4 billion Funds decline over the 5 years – starting at $2.8 billion in FY 16-17 and declining to $2.5 billion in FY 19-20.
Designated Health Programs	$2 billion federal funds	$4 billion total funds
DELIVERY SYSTEM TRANSFORMATION & ALIGNMENT		
Public Safety Net System Transformation and Improvement Program	$4 billion ($800 million/year)	$8 billion ($1.6 billion/year)
Other transformation & alignment programs ▪ Managed care ▪ Fee for service ▪ Workforce ▪ Housing ▪ Whole Person Care	$5 billion ($1 billion/year)	$10 billion ($2 billion/year)
Indian Health Services Uncompensated Care	$3.875 million ($.775 million)	$7.75 million ($1.55 million/year)
TOTAL	**$17.2 billion**	**$34.4 billion**

SHARED SAVINGS

The Federal-State Shared Savings initiative included in the concept paper seeks recognition of the Federal savings that California's waiver renewal generates and would allow the state to keep and reinvest portion of those savings in the Medi-Cal program for continued delivery system transformation. [See p. 34 of the concept paper.] DHCS argues that this concept has been used in commercial and public insurance markets (for example, Medicare, Duals) and should be explored in Medicaid.

California would receive a portion of Federal savings in the form of ongoing performance payments as long as net savings to the Federal government are demonstrated as calculated under the Waiver Budget Neutrality agreement. If California does not attain the agreed-upon level of savings to be shared, expenditures on the reinvestment Waiver strategies would need to be reduced in order to maintain budget neutrality. This is also a new concept and will likely be an area of negotiation between California and the federal government.

MANAGED CARE SYSTEMS TRANSFORMATION & IMPROVEMENT PROGRAM

DHCS is looking to transform disparate financial incentives by creating shared accountability across providers and plans. The proposals in this area are focused heavily on behavioral health care. Reforms include pay-for-performance based on quality and resource utilization, as well as shared savings between providers, managed care plans and the state that will lower the cost of care relative to expected cost trends. The state is also interested in rethinking the managed care capitation rate process to incentivize payments reform that promote investments to enable shared savings. For additional detail, see pages 14-17 of the concept paper.

The paper includes three specific strategies:

1. **Shared Savings Incentives with Managed Care Organizations.** The state would identify targeted populations and/or services for which they would like to see change in outcomes and cost, and increased shared accountability among plans, county services and providers. If the plan, in partnership with providers and the behavioral health system (joined in what would be similar to accountable care groups) is able to demonstrate costs below total costs of care and meet mutually determined outcome and quality targets, the plan would be eligible to receive shared savings incentive payments.

   Additionally, the state is interested in addressing social determinants of health through this proposal. The state would identify non-traditional services that a plan could provide and, depending on a demonstration of the impact on improved outcomes, would permit a plan to receive an incentive payment. Tenancy supports would be an example of non-traditional services and are discussed further in the "Increased Access to Housing and Supportive Services" section.

2. **Pay-for-Performance Strategies for Managed Care Plans to Implement with their Providers.** DHCS is proposing to standardize metrics for pay-for-performance (P4P) programs. The paper outlines a number of required and optional measures.

3. **Integrate Behavioral Health and Physical Health at the Plan/county and Provider Levels.** The paper includes two integration approaches that do not need to be implemented simultaneously:

   - Plan/County Coordination Model. Participating Medi-Cal managed care plans would be required to work with county mental health plans to support Medi-Cal members with identified mental health issues. The managed care plans and county mental health plans would be jointly responsible for improving health outcomes and reducing avoidable emergency room visits and hospital stays by promoting care coordination and information sharing for members. An incentive pool would be allocated to both the managed care and county mental health plans under two incentive payment streams: 1) for developing a process and procedures to affect change and 2) for meeting joint performance goals for a set of quality and outcome measures. The quality incentive payments would be allocated after plans have met the measures and would be the majority of payments. Over time, this model would evolve to a risk based shared savings model.
   - Provider Integration Model. This model would encourage physical health and mental health plans to implement an integrated care model for patients with serious mental health and other chronic health conditions at the provider level. Medi-Cal managed care plans would offer incentives to increase physical health and behavioral health integration, using either a coordination or co-location approach, and could include the use of telehealth.

FEE-FOR-SERVICE TRANSFORMATION & IMPROVEMENT PROGRAM

California is proposing to improve care delivery in the fee-for-service program in two key areas – dental services and maternity care. Details can be found on pages 17-18 of the concept paper.

Medi-Cal Dental. California is proposing to implement a statewide provider incentive payments for the provision of dental preventative services. Dental providers would be eligible to receive incentive payments for providing increased access to dental services. Incentive payments would available for dental providers who are new Medi-Cal providers and provide specified levels of access to Medi-Cal beneficiaries (e.g. dedicate X percent of their practice for Medi-Cal members). In addition, for existing Medi-Cal dental providers, incentives would be available to increase the number of Medi-Cal members they treat. Please note that this mirrors some of the workforce proposals.

Maternity Care. California proposes to pilot a hospital incentive program for maternity care. The program would provide bonus payments to hospitals that meet or exceed quality threshold baselines on four performance measures: 1) early elective delivery, 2) cesarean section rate for low-risk births, 3) vaginal births after cesarean delivery rate, and 4) unexpected newborn complications in full term babies.

PUBLIC SAFETY NET SYSTEM TRANSFORMATION & IMPROVEMENT PROGRAM

The Delivery System Reform Incentive Program (DSRIP) is a five-year, federal pay-for-performance quality improvement initiative for California's 21 public hospitals in the existing waiver, which provides $3.3 billion over five years. DSRIP funding has been used to expand access to primary care, improve quality of care and health outcomes and increase efficiency at public hospitals.

Under Medi-Cal 2020, California is proposing to build upon DSRIP by creating a "public safety net system transformation and improvement program." In addition to California's 21 public hospitals, the 42 healthcare districts, known as non-designated public hospitals, would participate in the Public Safety Net System Transformation and Improvement Program. Due to the diversity of district hospitals, DHCS is proposing to implement a "tiered" approach for these hospitals' participation in the successor DSRIP. Additionally, California is requesting a funded planning period of up to 12 months to give interested district hospitals time to get the tools and technical assistance in place to participate.

For additional details on the public safety net system transformation and improvement program, please see pages 18-21 of the concept paper.

DHCS's goal is to drive even further change in public safety net systems, while also providing a more standardized approach and outcomes focused metrics. California is proposing five core domains to drive quality improvement and population health advancement:

1. **System Redesign.** Projects in this domain are focused on redesigning ambulatory care for primary and specialty care, integration of post-acute care, and integration of behavioral health and primary care services.

2. **Care Coordination for High Risk, High Utilizing Populations.** Examples of such populations includes foster children, individuals who have recently been incarcerated and patients with advanced illness. Objectives for this domain are focused on care management, reducing avoidable acute care utilization, palliative care, and patient experience and improving health indicators for chronically ill patients, including those with mental health and substance use disorders.

3. **Prevention.** Areas of emphasis in this domain are focused on areas such as cardiac health, cancer, and perinatal care.

4. **Resource Utilization Efficiency.** This domain is focused on eliminating the use of ineffective or harmful clinical services and curbing the overuse and misuse of clinical services. Projects in this domain will focus on appropriate use of antibiotics, high cost imaging and pharmaceuticals.

5. **Patient Safety.** This domain is focused on improving performance on metrics related to potentially preventable events and reducing inappropriate surgical procedures.

WORKFORCE DEVELOPMENT PROGRAM

The concept paper acknowledges a number of California's workforce challenges for Medi-Cal providers – including enrollment growth in Medi-Cal and increased competition for providers as a result of the Affordable Care Act, an aging workforce, an aging Medi-Cal population, geographic and cultural differences between provider and member distribution, and a long educational "pipeline" for some professions. Additional specifics on workforce development can be found on pages 22-24 of the concept paper.

To address these challenges, California proposes:

Incentives to Increase Provider Participation. DHCS wants to provide financial incentives to encourage new providers to accept Medi-Cal members and to encourage existing Medi-Cal providers to increase the number of Medi-Cal members they are serving. The incentives would target geographic areas with the greatest need and professions and specialties that are the most challenging to recruit providers. Additional emphasis would be on racially/ethnically diverse health professionals.

Financial Incentives for Non-Physician Community Providers. California would provide incentives to managed care plans to support non-physician community providers, including Community Health Workers and Peer Support Specialists. The paper highlights that expanded use of peer support in mental health and substance use disorder treatment, in particular, can further improve care coordination between primary health and behavioral health needs of patients.

Screening Brief Intervention, and Referral to Treatment (SBIRT) Training and Certification. California would expand SBIRT to make it available in additional settings and to make the trainings and certification available to a broader spectrum of providers. Currently, SBIRT is only required for Medi-Cal enrollees in primary care settings.

Training:

- Targeted Training for Non-Physician Health Care Providers. Voluntary training for non-physician health care providers such as In-Home Supportive Services (IHSS) workers, Community Health Workers, patient navigators, Peer Support Specialists, and others
- Palliative Care Training. Increased voluntary training programs on palliative care for physicians, nurses and other appropriate licensed providers.
- Expanded Residency Training Slots. California would provide targeted funding for existing and new residency programs at teaching health centers or primary care sites, particularly those for which federal Health Resources and Services Administration (HRSA) grant funding ends in 2015.

In addition, under the waiver renewal, California would provide incentives for additional training slots in geographic areas of the state where there are shortages in the number of physicians that participate in Medi-Cal, and for the specialties that are in the greatest need. The programs would further target medical school graduates to take positions in racially and economically diverse areas in order to improve access to culturally appropriate care for Medi-Cal members.

Incentives to Expand the Use of Telehealth. Under the waiver, California will provide incentives for telehealth. First priority is for geographic areas or certain specialists where access is more limited. The state will pilot-test incentive payments to encourage the use of telehealth and require corresponding reporting of outcome data.

INCREASED ACCESS TO HOUSING AND SUPPORTIVE SERVICES

As part of DHCS's vision for improving care coordination for California's most vulnerable populations, the concept paper proposes a new approach to providing care to individuals experiencing homelessness, including tenancy supports and intensive medical case management. These concepts are detailed on pages 24-26 of the state's paper. The state will partner with Medi-Cal managed care plans, counties, community organizations, and Federal partners to develop county-specific pilot programs in counties where there is a commitment from the full spectrum of stakeholders that will provide homeless individuals with the support to find and maintain housing and gain consistent access to needed community supports. DHCS anticipates that Medi-Cal managed care plans will see cost savings in serving homeless individuals and will designate a portion of those savings to reinvest in the supportive services that will assist homeless individuals in maintaining their health, including housing supports. Details include:

Target population. 60,000 at risk Medi-Cal members, including: individuals who are currently homeless or will be homeless upon discharge from institutions (hospital, sub-acute care facility, skilled nursing facility, rehabilitation facility, Institutions for Mental Disease (IMD), or county jail) AND a) have repeated incidents of emergency room use, hospitals admissions, or nursing facility placements; OR b) have two or more chronic conditions; OR c) mental health or substance use disorders. DHCS notes that this population may include veterans.

Intervention Strategies:

- Managed Care Plans. Through the waiver, DHCS would provide access to intensive housing-based care management services and intensive care management to tenants who meet target population criteria. Managed care plans will have the option of paying for non-traditional services such as nutritional services, continuous nursing, personal care, habilitation services, and tenancy supports (like outreach and engagement, housing search assistance, stabilization,

paying rent and bills on time, not disruptive to other tenants, maintaining SSI and other benefits).

- Regional Housing Partnerships. Local partnerships may be eligible for incentive funding through the waiver to establish and support regional integrated care partnerships specifically focused on housing. These partnerships would be required to include managed care plans, county health agencies (including county behavioral health), cities, hospitals, and housing and social services providers. A region could include a single county, a portion of a large county, or counties working together. The lead entity could be a county, managed care plan, local non-profit coordinating organization or foundation. Regional partnerships would include a number of elements:
    - DHCS would request proposals from counties and plans to partner. These partnerships would build on the section 2703 health homes programs (also known as 90/10 health homes) where appropriate.
    - Programs would support housing as a health care intervention approach.
    - Counties/plan would receive incentive payments under the pilot to create and maintain the partnership, including support to develop MOUs/MOAs/contracts, create shared data systems and develop processes for assisting eligible Medi-Cal members in moving to permanent housing.
    - Counties and plans would receive performance payments to the extent that a pilot achieves specific performance metrics (e.g. members of the target population accessing subsidized housing units, certain HEDIS or other quality measures, reduction is use of ED and other institutional services).
    - Each pilot must include a shared savings funding pool made up of contributions from plans and counties based on savings generated.

  DHCS envisions the savings pool will provide support for services like respite care; fund support for long-term housing, including housing subsidies; finance further expansion of housing-based case management; and leverage local resources to increase access to subsidized housing units. The savings pool can also provide long-term rental subsidies and assistance.

WHOLE PERSON CARE PILOTS

The concept paper also provides additional detail about Whole Person Care Pilots. Regional partnerships – a county or group of counties, jointly working with Medi-Cal managed care plans in the region – would be eligible to pursue Whole Person Care pilots. The Whole Person Care Pilot section is on pages 27-28 of the concept paper. Details include:

Pilot Partnerships. Pilots would be required to include all of the following participants, as appropriate to the targeted population:

- Medi-Cal managed care plans (in counties with more than one plane, the pilot must include at least two plans participating)
- County behavioral health systems

- Hospitals
- Clinics and doctors
- Other medical providers
- Social services agencies and providers
- Public health agencies and providers
- Non-medical workforce
- Housing providers/local housing authorities
- Criminal justice/probation
- Other community-based organizations with experience serving high need populations.

Critical Elements. Proposals must have a clear governance structure that describes the role of the various partner entities and proposed financing arrangements. Pilots must include a detailed plan for achieving care coordination and integration, including behavioral health integration.

Target Population. Pilots must describe how they will identify the target population who frequently use multiple systems, what data will be used, local partnerships, and minimum enrollment target. At a minimum, the target population must be at least 50 Medi-Cal members or the top 1 percent of emergency/inpatient users.

Patient Centered Care. Pilots must specify how they plan to structure care teams; how they will create individualized care plans for each patient that addresses the medical, behavioral, and social needs of the patient; and how they will select a single accountable individual on the care team to ensure the care plan is carried out in a culturally and linguistically competent manner. Pilot will need to integrate with the section 2703 health home programs (or 90/10 health home) to the extent that the county is participating in the health home project.

Social Supports. Pilots must assess the needs of the target population and provide additional supports such as social services (CalFresh, child care, homeless services, foster care supports, job training); benefit advocacy; outreach and engagement strategies; housing and enhanced care coordination and tenancy supports; criminal justice; and public health.

Shared Data and Evaluation. Pilots will need to describe how data will be shared across agencies and how shared data will be used for care coordination and patient-centered care. Specific evaluation criteria includes:

- Improvements in health outcomes, health status and disparities
- Success at enrolling individuals for eligible social supports
- Housing
- Impacts on total cost of care, scalability and sustainability beyond the waiver term

Financial Flexibility. Pilot sites must identify additional services and supports that they expect to offer in addition to non-traditional Medicaid services and work with DHCS to establish appropriate reimbursement mechanisms. Pilot partners must agree to reinvest any savings into areas that further support whole person care.

PUBLIC SAFETY NET GLOBAL PAYMENT FOR THE REMAINING UNINSURED

The concept paper includes a proposal to create Public Safety Net Global Payments for the remaining uninsured. The Global Payments are detailed on pages 29-33 of the concept paper. DHCS is interested moving away from volume-based and cost-based care and, instead, towards risk-based care for the remaining uninsured. DHCS intends to incentivize coordination of care for the remaining uninsured, including rewarding the provision of primary care. Specifically, DHCS is proposing to combine two funding sources – DSH and SNCP funds – into a Public Safety Net Global Payment for the remaining uninsured.

Disproportionate Share Hospital (DSH) Funding Background

Currently, DSH payments are not part of the existing waiver. However, DHCS is proposing to include those payments in Medi-Cal 2020. DSH funds currently provide reimbursement for hospital-based services.

DSH payments are federal payments that provide additional reimbursement to those hospitals that serve a significantly disproportionate number of low-income patients (both Medicaid and uninsured). States receive an annual federal DSH allotment to pay for a portion of the uncompensated care costs. California's allotment is approximately $1.188 billion, with designated public hospitals receiving approximately $1.176 billion (federal funds).

Federal health care reform included provisions to reduce DSH; those reductions are slated to begin in 2016-17. The DSH reductions increase each year until 2022 when they stabilize. Nationally, the DSH cut is approximately 50 percent of the current DSH total. It is not yet clear how the DSH reduction formula will work in the context of state Medicaid expansions (i.e. how the DSH cuts will be implemented in states that chose not do a Medicaid expansion v. those states, like California, that opted to expand Medicaid).

Safety Net Care Pool Background

The Safety Net Care Pool was an element of the 2005-2010 waiver, as well as the current waiver. The state and designated public hospitals are eligible to claim uncompensated costs of services to the uninsured using certified public expenditures (CPEs). Private hospitals and non-designated public hospitals cannot access the SNCP.

At the height of the SNCP, over $900 million was available for the state and designated public hospitals to claim. In 2015, less than $636 million in federal funding is available. The state is able to claim $400 million per year out of the SNCP. Public hospitals are eligible to claim approximately $236 million in the final 16 months of the waiver.

Global Payments Overview

The following chart provides an overview of how DSH and SNCP are used today and how they compare to the global payments as outlined by DHCS:

	DSH today	SNCP today	Global Payments
Uncompensated costs related to Medi-Cal	✓		
Uncompensated costs related to the uninsured	✓	✓	✓
Uncompensated costs related to undocumented persons	✓		✓
Hospital costs	✓	✓	✓
Non-hospital costs		✓	✓
Intergovernmental transfers (IGTs)	✓		✓
Certified Public Expenditures (CPEs)	✓	✓	

Elements of this new global payment include:

- Each individual public hospital system would have its own "global payment" from within the pool of overall federal funding. Individual payments would allow each hospital system more certainty about its budget and how much federal funds would be available.
- Funding would be claimed quarterly with the public hospital providing the necessary IGT, which moves away from today's cost-based methodology.
- A public hospital system would achieve "points" for threshold service targets, with a base level of points required for each system to earn their full global budget.
- Partial funding would be available for partial achievement of points.
- Points would allow for the continuation of traditional services but encourage more appropriate and innovative care. Additionally, point values would be developed for innovative or alternative services where there is currently little to no reimbursement.

Services. The state will establish baseline threshold point targets for services currently provided today. DHCS has grouped services into four categories.

- **Category 1. Traditional Outpatient:** Face-to-face outpatient visits an individual could have at a public hospital facility. Specifics include: a) non-physician practitioner (RN, PharmD, Complex Care Management); b) traditional, provider-based primary care or specialty care visit; c) mental health visit; d) dental; e) public health visits (TB clinic, STC screening); f) post-hospital discharge/post-ED primary care; g) emergency room/urgent care; h) outpatient providers/surgery (wound check), provider performed diagnostic procedures, other high-end ancillary services (e.g. chemo, dialysis)
- **Category 2. Non-Traditional Outpatient:** Outpatient encounters where care is provided by nontraditional providers or in nontraditional or virtual settings. Specifics include: a) community health worker encounters; b) health coach encounters; c) care navigation; d) health education and community wellness encounters; e) patient support and disease management groups; f) immunization outreach; g) substance use disorder counseling groups; h) group medical visits; i)

wound check; j) pain management; k) case management; l) mobile clinic visits; m) palliative care; n) home nursing visits post-discharge; o) paramedic treat and release encounters.

- **Category 3. Technology-Based Outpatient:** Technology-based outpatient encounters that rely mainly on technology to provide care. Examples include: a) call line encounters (nurse advice line); b) texting; c) telephone and email consultations between provider and patient; d) provider-to-provider eConsults for specialty care; e) telemedicine; f) video-observed therapy.

- **Category 4. Inpatient and Facility Stays.** Specifics include: a) recuperative/respite care days; b) sober center days; c) sub-acute care days; d) skilled nursing facility days; d) general acute care and acute psychiatric days; e) higher acuity inpatient days in ICU and CCU; f) highest acuity days and services such as trauma, transplant and burn

Threshold. To determine threshold amounts, each system would estimate the volume and mix of uninsured services likely to occur based on historical data and projected estimates of uninsured care needed. The intent is to determine the level of services that would have been provided absent this proposal. The thresholds would need to be adjusted over time to account for the federal DSH reductions.

Evaluation and Accountability. The proposal would also include an evaluation component. California would be seeking to demonstrate that shifting payment away from cost and toward value can encourage care in more appropriate settings, to ensure that patients are seen in the right place and given the right care at the right time. DHCS would establish clear metrics to measure whether the pooled funding is successful. The evaluation would focus on the resource allocation and workforce investments and the extent to which investments shift the balance of primary and specialty care toward longitudinal care in primary care settings. Potential metrics:

- Ratio of new to follow-up appointments within specialty care
- Average time to discharge from specialty care
- Ratio of primary care to emergency room/urgent care visits
- Mental health/substance use disorder visits
- Inpatient stays related to ambulatory sensitive conditions
- Non-emergency use of the emergency room
- Use of non-traditional workforce classifications (such as community health workers)
- Expansion of the roles/responsibilities (within the scope of practice) for traditional workforce classifications

GOALS AND METRICS

Medi-Cal 2020 is a demonstration waiver, and as such the federal government requires an evaluation of the waiver. DHCS is developing performance metrics – including statewide measures, regional measures, plan measures and provider measures. The state is committed to measuring improvement through the initiatives outlined above. The paper does not provide detail on the measures, but DHCS indicates they are looking at reducing preventable events (i.e. readmissions and inappropriate emergency room use) and improved access to timely care.

NEXT STEPS

DHCS's March 16 concept paper is a draft document. They are soliciting feedback from stakeholders and intend to formally submit the Medi-Cal 2020 waiver proposal to CMS on March 27, 2015. Once the proposal is submitted to CMS, California will begin its federal negotiations in earnest. In April, DHCS will be doing a webinar for CMS similar to the stakeholder webinar on March 18 to formally walk through the proposal. It is not unusual for waiver negotiations to take several months. DHCS anticipates communicating with stakeholders – formally and informally over the next several months – as they get a better understanding of how CMS views various components of the waiver proposal.

When negotiations between the state and federal governments conclude on the major concepts, CMS will create the Special Terms and Conditions (STCs), the legal document governing the waiver. Finally, once the STCs are complete, state implementation of the waiver can begin. The goal is to begin implementation in November 2015.

Additionally, the California Legislature will be involved in the waiver development and implementation. Currently there are two bills – AB 72 by Assembly Member Rob Bonta and SB 36 Senator Ed Hernandez – that make changes to state law in order to implement Medi-Cal 2020. Each author chairs the Health Committee in his respective house. Both bills are currently in spot bill form; details will be added as details emerge on the discussions between California and CMS.

Hurst Brooks Espinosa, LLC will continue to provide updates to counties and CSAC on details that on California's Medi-Cal 2020 Waiver renewal – the final waiver submission, the political and policy negotiations that unfold over the next several months, and the legislative process.

For additional questions, please contact Kelly Brooks-Lindsey at kbl@hbeadvocacy.com or 916.272.0011.

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March 18, 2015

To: CSAC Health and Human Services Policy Committee

From: Farrah McDaid Ting, Legislative Representative
Michelle Gibbons, Legislative Analyst

Re: Proposed Tobacco-Related Legislation in 2015

Background. County, state, and federal public health departments have worked for decades to prevent tobacco use and assist those who use tobacco in ceasing the behavior. Public health officials also work to mitigate the effects of tobacco use in our communities and treat the illnesses associated with tobacco use.

In recent years, the rise of additional methods of tobacco and nicotine consumption have necessitated a new look at the tobacco issue. E-cigarettes, or "vaping," whereby by blast of vaporized nicotine is delivered to the user, has risen significantly. According to a point-in-time tobacco retail observation survey in 2013, funded by the California Tobacco Control Program (CTCP), of 7,393 tobacco retailers, 45.7 percent sold e-cigarettes.

The health effects of these newer nicotine delivery systems are unclear, but public health officials throughout the United States are moving to gather data. The U.S. Food and Drug Administration has also proposed to extend their authority over tobacco products to cover additional products such as e-cigarettes. This move would allow the agency to regulate e-cigarettes in the same way as tobacco products, including imposing age limitations and advertising restrictions.

Given this rise in consumption via vaping, especially by youth who are attracted to the flavored nicotine products, the California Legislature is taking an interest in vaping and tobacco issues (see "Tobacco Legislation" attachment). Counties are also at the forefront of vaping legislation, with Placer County moving last month to ban e-cigarettes and vaping in all county buildings.

Process. The CSAC Health and Human Services Policy Committee is charged with engaging on public health issues related to counties in California. The e-cigarette issue is a hot topic in both the state legislature and at the local level, and this item is intended as an information only agenda item at this time.

Attachments:
CSAC Tobacco Legislation Chart
March 18, 2015
"Vaping and Health, What Do We Know About E-Cigarettes?"
Environmental Health Perspectives: Volume 122, No. 9, September 2014
"Placer County Bans E-Cigarettes from Public Buildings and Vehicles"
Sacramento Bee, March 10, 2015

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Tobacco-Related Legislation

Bill Author	Description	CSAC Position	Status
AB 48 Stone, Mark D	Cigarettes: single-use filters. (Amended: 2/13/2015) Would state findings and declarations of the Legislature regarding the health and safety hazards to residents of the state related to cigarettes utilizing single-use filters. The bill would prohibit a person or entity from selling, giving, or in any way furnishing to another person of any age in this state a cigarette utilizing a single-use filter made of any material, including cellulose acetate, or other fibrous plastic material, and any organic or biodegradable material.	Watch	2/17/2015 - Re-referred to Com. on G.O.
AB 216 Garcia, Cristina D	Product sales to minors: vapor products. (Introduced: 2/2/2015) Current law prohibits the sale of electronic cigarettes to people under 18 years of age. Current law defines "electronic cigarette" as a device that can provide an inhalable dose of nicotine by delivering a vaporized solution. This bill would prohibit the sale of any device intended to deliver a nonnicotine product in a vapor state, to be directly inhaled by the user, to a person under 18 years of age. Because this bill would create a new crime or infraction, the bill would impose a state-mandated local program. This bill contains other related provisions and other current laws.	Watch	2/9/2015 - Referred to Com. on G.O.
AB 261 Allen, Travis R	Cigarettes and tobacco products: retailers: licenses. (Introduced: 2/9/2015) The California Cigarette and Tobacco Products Licensing Act of 2003 requires a retailer to have and maintain a license from the State Board of Equalization to engage in the sale of cigarette and tobacco products in California. This bill would make a nonsubstantive change to that provision.	Watch	2/10/2015 - From printer. May be heard in committee March 12.
AB 768 Thurmond D	Tobacco Free Baseball Act. (Introduced: 2/25/2015) Would prohibit the use of tobacco products, as defined, including smokeless tobacco, in a baseball stadium, which includes the physical area in which a professional, collegiate, high school, or other organized baseball game or practice is occurring. The bill would require a baseball stadium to have posted at every entrance a conspicuous sign clearly communicating that the use of tobacco products, including smokeless tobacco, is prohibited. The bill provides that, if any provision or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.	Watch	3/19/2015 - Re-referred to Coms. on A.,E.,S.,T., & I.M. and G.O. pursuant to Assembly Rule 96.
AB 1162 Holden D	Medi-Cal: tobacco cessation. (Introduced: 2/27/2015) Would provide that tobacco cessation services are covered benefits under the Medi-Cal program and would require that those services include, at a minimum, unlimited quit attempts, which would be defined to include at least 4 counseling sessions and a 90-day treatment regimen of any medication approved by the federal Food and Drug Administration for tobacco cessation.	Pending	3/2/2015 - Read first time.
AB 1238 Linder R	Cigarette and tobacco products taxes. (Introduced: 2/27/2015) The Cigarette and Tobacco Products Tax Law imposes a tax on every distributor of cigarettes and tobacco products at specified rates, including additional taxes imposed under the Tobacco Tax and Health Protection Act of 1988 (Proposition 99) and the California Families and Children Act of 1998 (Proposition 10). Current law provides definitions that govern the construction of this law. This bill would make a nonsubstantive change to this provision regarding definitions under the law.	Watch	3/2/2015 - Read first time.

AB 1278 Gray D	Cigarettes and tobacco products: identification requirements. (Introduced: 2/27/2015) Current law requires a person selling or distributing, or engaging in the nonsale distribution of, tobacco products directly to a consumer in the state through the United States Postal Service or package delivery service to verify that the purchaser or recipient of the product is 18 years of age or older. This bill would provide that, for the purposes of these requirements, if a customer or recipient provides an identification card issued by the United States Armed Forces as proof of age and the identification card lacks a physical description, but includes date of birth and a photo, further proof of age is not required.	Watch	3/2/2015 - Read first time.
AB 1396 Bonta D	Medi-Cal. (Introduced: 2/27/2015) Current federal law requires that a state plan for medical assistance provide methods and procedures relating to the utilization of, and the payment for, care and services available under the plan as may be necessary to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that care and services are available to the general population in the geographic area. This bill would state the intent of the Legislature to enact legislation to align state law with federal law, as specified above, and to require an independent, third party to establish standardized metrics on access to care and quality of care, and to assess services using those metrics.	Watch	3/2/2015 - Read first time.
SB 24 Hill D	STAKE Act: electronic cigarettes. (Introduced: 12/1/2014) Would extend the STAKE Act to sales of electronic cigarettes to minors. The bill would require the State Department of Public Health to enforce the STAKE Act's provisions with regard to sales of electronic cigarettes commencing July 1, 2016. This bill contains other related provisions and other existing laws.	Watch	3/10/2015 - Set for hearing April 8. *Hearing: 4/8/2015 1:30 p.m. - John L. Burton Hearing Room (4203) SENATE HEALTH, HERNANDEZ, Chair*
SB 140 Leno D	Electronic cigarettes. (Amended: 3/10/2015) Would change the STAKE Act's definition of tobacco products to include electronic devices, such as electronic cigarettes, that deliver nicotine or other substances, and make furnishing such a tobacco product to a minor a misdemeanor. This bill contains other related provisions and other existing laws.	Watch CSAC Bulletin 1/30/15.	3/18/2015 - Set for hearing April 8. *Hearing: 4/8/2015 1:30 p.m. - John L. Burton Hearing Room (4203) SENATE HEALTH, HERNANDEZ, Chair*
SB 151 Hernandez D	Tobacco products: minimum legal age. (Introduced: 1/29/2015) The Stop Tobacco Access to Kids Enforcement (STAKE) Act, establishes various requirements for distributors and retailers relating to tobacco sales to minors. Current law requires the State Department of Public Health to conduct random, onsite sting inspections of tobacco product retailers with the assistance of persons under 18 years of age. This bill would extend the applicability of those provisions to persons under 21 years of age. The bill would authorize the State Department of Public Health to conduct random, onsite string inspections of tobacco product retailers with the assistance of persons under 21 years of age.	Watch	3/18/2015 - Set for hearing April 8. *Hearing: 4/8/2015 1:30 p.m. - John L. Burton Hearing Room (4203) SENATE HEALTH, HERNANDEZ, Chair*
SB 591 Pan D	Cigarette and tobacco products taxes: California Tobacco Tax Act of 2015. (Introduced: 2/26/2015) Would, on or after the first day of the first calendar quarter commencing more than 90 days on or after the effective date of the bill, impose an additional tax on the distribution of cigarettes at the rate of $0.10 for each cigarette distributed which would be $2.00 per pack; would require a dealer and a wholesaler to file a return with the State Board of Equalization showing the number of cigarettes in its possession or under its control on that date, and impose a related floor stock tax; and would require a licensed cigarette distributor to file a return with the board and pay a cigarette indicia adjustment tax at the rate equal to the difference between the existing tax rate and the tax rate imposed by this bill for cigarette tax stamps in its possession or under its control on that date.	Pending	3/19/2015 - Set for hearing April 8. *Hearing: 4/8/2015 9:30 a.m. - Room 112 SENATE GOVERNANCE AND FINANCE, HERTZBERG, Chair*

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Vaping *and* Health

What Do We Know about E-Cigarettes?

Advertisements for e-cigarettes claim they help smokers curb their habit while inhaling only "harmless water vapor," but few tests have been conducted to confirm these claims. © Jack Ludlam/Alamy

As a pulmonologist with the San Diego Veteran's Affairs hospital, Laura Crotty Alexander has probably answered every possible question about smoking. Whether her patients were looking for ways to quit or simply wondering whether their current health problems might be related to smoking, Crotty Alexander provided answers.

A couple of years ago, however, her patients began asking new questions: Are electronic cigarettes safer than conventional cigarettes, and should they switch? "I didn't have the answers. As a physician and a researcher, that was very frustrating," Crotty Alexander says.

Physicians all over the country are encountering the same questions from their patients. Out of nowhere, it seems, e-cigarettes—or electronic nicotine delivery systems, as they are formally known—are appearing at gas stations, convenience stores, and anywhere else cigarettes are sold. Marketing statements may claim e-cigarettes offer health benefits by helping smokers quit, and all e-cigarette users inhale is "harmless water vapor."[1] The e-cigarette, it would seem, takes all the risk out of smoking.

Many environmental health scientists aren't so sure. Maciej Goniewicz, a toxicologist at the Roswell Park Cancer Institute in Buffalo, New York, says, "This is vapor, but only a small proportion of it is water." Mostly, he says, it's made up of propylene glycol and/or glycerin, the main ingredients in the "e-liquid" (or "e-juice") that is vaporized inside e-cigarettes. When heated, these solvents produce an aerosol resembling cigarette smoke.[2] Most e-liquids also contain flavorings and preservatives.[3,4]

"Most of what we know about e-cigarettes is from lab studies," Goniewicz says. "We don't know about the real health effects on the users of this product, especially on long-term users."

The newness of e-cigarettes means longitudinal studies about potential health dangers are still in the distant future. Meanwhile, the existing literature about the safety of the devices consists of small studies on e-liquids and e-cigarette emissions. It remains unknown exactly how e-cigarettes and their related emissions compare with conventional cigarettes.

Despite the lack of health data, many researchers assume e-cigarettes are less dangerous than conventional cigarettes. Gerry Stimson, a public health social scientist at Imperial College London, explains, "When you burn vegetable matter, you inhale lots of nasty things into your lungs." Because e-cigarettes only heat a liquid rather than burning tobacco leaves, he says, it creates fewer hazardous particles that can be inhaled.

"The vapor does not appear to be benign, but it does seem to be the lesser of two evils when compared to cigarettes," Crotty Alexander says.

Stimson adds, "At issue is a matter of weighing up potential risks against potential health benefits. Small and sometimes not so small risks are associated with all sorts of pharmacological and other health and social interventions, but the necessary precautionary principle needs to be weighed against potential benefits."

Of course, saying something is safer than smoking cigarettes isn't exactly setting a high bar. The Centers for Disease Control and Prevention estimates that cigarette smoking causes one in five U.S. deaths each year, including deaths resulting from secondhand smoke exposure.[5] Smoking is a leading risk factor in chronic obstructive pulmonary disease, lung cancer, and cardiovascular disease.[6] It's the leading preventable cause of premature death in the United States and one of the leading causes around the world.[6]

A Boom in Popularity

Against a backdrop of increasing awareness of the health dangers of cigarettes and legal crackdowns on public smoking, Chinese pharmacist Hon Lik first developed an electronic alternative to traditional cigarettes in 2003.[7] E-cigarettes entered the U.S. market in 2007.[8]

The devices come in a variety of shapes and sizes, but all are variations on the same general theme: A heating element at one end aerosolizes a liquid nicotine solution, and the vapor is inhaled through a mouthpiece. "We see e-cigarettes as a single group of products, but there are hundreds of brands and many different generations and models," Goniewicz says. "There are also huge variations in how people use these products."

E-cigarettes were originally sold almost exclusively online and were not covered by existing tobacco regulations. At first, their popularity grew slowly, as small numbers of smokers turned to them to replace or supplement their tobacco smoking habit. As companies such as Reynolds American and Lorillard began showing interest in the devices, advertising increased, and the products moved into brick-and-mortar stores.[9] In a short time, e-cigarettes' unconfirmed reputation as a smoking-cessation aid and a "healthy" alternative to

Although manufacturers offer many different designs of e-cigarettes, all involve the same basic concept: A heating element at one end aerosolizes a liquid nicotine solution, and the vapor is inhaled through a mouthpiece. © AP Photo/Frank Franklin II

cigarette smoking has widely increased their popularity.[10]

Manufacturers can make the nicotine solution flavorless, but many companies add flavors, ranging from the sophisticated (mint chocolate truffle and whiskey) to the baldly juvenile (bubble gum, gummy bears, and cotton candy). A congressional report from spring 2014 accused e-cigarette manufacturers of using these flavors to appeal to youth,[11] a marketing strategy that is prohibited for tobacco cigarettes because it is so effective at attracting young users.[12] In contrast to tobacco products, e-cigarette sales are not age-restricted, and in 2012 an estimated 1.78 million students in grades 6–12 had tried the devices.[13]

Increases in "vaping" (as e-cigarette users call their habit) have not been matched by available knowledge about the physiological effects of the practice. And when investigators tried to quantify exposures in e-cigarette users, they rapidly ran into trouble, says tobacco researcher Stanton Glantz of the University of California, San Francisco.

For one thing, each manufacturer of e-cigarettes has a different design for the device and e-liquid,[14] which alters how much of the vapor and its chemical load is inhaled with each puff.[15] An individual's unique vaping behaviors also help determine how much they inhale.[16] The labels on refill cartridges don't always accurately reflect the amount of nicotine found in the e-liquid,[2,17,18,19] nor does the amount of nicotine found in the liquid appear to correlate with the amount of nicotine found in the vapor.[20]

What We've Learned So Far

Although these difficulties have slowed researchers in their studies, they haven't stopped them. Goniewicz and others started with what they already knew. Previous research on propylene glycol, one of the most commonly used constituents of e-liquids, showed it can cause eye and lung irritation.[21] In its product safety assessment for propylene glycol, the Dow Chemical Company recommends individuals avoid inhaling the chemical.[22]

A new study by Goniewicz and colleagues in *Nicotine & Tobacco Research* reveals that potentially toxic carbonyls can form when e-liquids are heated to high temperatures. In early models of e-cigarettes, the heating element didn't get warm enough to create these compounds. However, some newer "variable voltage" models allow users to increase the temperature of the heating element to deliver more nicotine—which also generates carbonyls.[23]

Carbonyls, which consist of a carbon atom double-bonded to an oxygen atom, are found in a variety of organic and organometallic compounds. The carbonyls identified by Goniewicz and colleagues included formaldehyde, acetaldehyde, acetone, and butanol. Propylene glycol–based e-liquids generated higher levels of carbonyls than other fluids, with levels of carcinogenic formaldehyde observed in the range seen in tobacco smoke.[23]

Interestingly, the researchers also noted that one e-liquid produced no detectable carbonyls at higher temperatures. This fluid was predominantly polyethylene glycol and contained less propylene glycol and glycerin than the other samples.[23]

Other investigators are interested in the flavorings and preservatives used in e-liquids. Although the U.S. Food and Drug Administration (FDA) classifies these additives as "generally recognized as safe," this classification typically is based on ingestion, whereas inhalation may create a different toxicity profile.[14] A few studies have identified various nicotine-related degradation products and other impurities in e-liquids and vapors,[17,18,24] although some researchers have concluded these impurities occur at levels unlikely to cause harm.[3]

In vitro research has indicated the potential for cytotoxic effects of e-liquid flavorings. In one study investigators screened 35 samples of different e-cigarette solutions in three types of cells: human pulmonary fibroblasts, human embryonic stem cells, and mouse neural stem cells. Although the nicotine in these e-liquids didn't show evidence of cytotoxicity, some of the flavorings did. Both types of stem cells were also far more sensitive to the chemicals than the adult lung cells.[25] However, far more research is needed to confirm these findings and, if confirmed, what they mean for human health.

Fine and ultrafine particles produced during combustion of plant matter are one of the major contributors to respiratory and cardiovascular risk from smoking tobacco.[26] Although e-cigarettes don't involve combustion, they do still produce particles of various types.[9] A team of researchers from Washington University in St. Louis reported that ultrafine particles of water, nicotine, and solvent appeared to deposit in the lungs in a similar pattern as the ultrafines found in tobacco smoke.[26]

In a 2013 study, cell biologist Prue Talbot of the University of California, Riverside, found another type of nanoparticle in the vapor from e-cigarettes: Analysis revealed a high concentration of heavy metals and silicates. It turned out these metal nanoparticles came from the heating element, which consisted of a nickel–chromium wire coated in silver and soldered with tin. During exposure to the heating element, the e-liquid appeared to pick up bits of metal, which then were carried in the aerosol.[27]

Exposure Symptoms

Despite the lack of human health studies, reports from e-cigarette users indicate the potential for adverse side effects. When Talbot surveyed three different online vaping forums, she found 405 mentions of symptoms after using e-cigarettes. Although 78 were positive, and 1 was neutral, the other 326 symptoms were negative, with users most frequently complaining of headache, respiratory tract irritation, and changes in appetite.[28]

Given the popularity of e-cigarettes among teens and young adults, safety studies in adult users—even if they existed—would not necessarily reflect potential health risks of e-cigarettes for younger populations, according to allergist and pediatrician Chitra Dinakar of Children's Mercy Hospital in Kansas City, Missouri. "Generally, young people are more sensitive to chemicals," Dinakar says.

Kevin Chatham-Stephens, an officer with the Epidemic Intelligence Service at the Centers for Disease Control and Prevention, is tracking calls to poison control centers in relation to e-cigarette exposures.

Comparison of sample toxicants emitted by tobacco cigarettes and e-cigarettes

Toxic compound	Tobacco cigarette (µg in mainstream smoke)	E-cigarette (µg per 15 puffs*)	Average ratio (conventional vs electronic cigarette)
Formaldehyde	1.6–52	0.20–5.61	9
Acetaldehyde	52–140	0.11–1.36	450
Acrolein	2.4–62	0.07–4.19	15
Toluene	8.3–70	0.02–0.63	120
NNN**	0.005–0.19	0.00008–0.00043	380
NNK**	0.012–0.11	0.00011–0.00283	40

* The authors assumed smokers of e-cigarettes would take an average of 15 puffs per vaping session, corresponding to smoking one tobacco cigarette.
** Tobacco-specific nitrosamine, a carcinogenic compound that originates in the curing and processing of tobacco.
Adapted from Goniewicz et al. (2014)[4]

Last spring he published the first data on child exposures to e-cigarettes and their components. In the *Morbidity and Mortality Weekly Report*, Chatham-Stephens and colleagues reported that calls to U.S. Poison Control Centers related to e-cigarettes increased from 1 call in September 2010 to 215 in February 2014. Just over half the reported e-cigarette exposures were to the e-liquids or the vapor. He says, "We want to generate awareness for clinicians and consumers about potential health risks, and to keep in mind potential adverse health effects."

At this point physicians are most concerned about acute nicotine toxicity, symptoms of which can include agitation, rapid heartbeat, seizures, nausea, and vomiting.[30] The authors of a case report of nicotine poisoning in an infant call on doctors to educate patients about the hazard posed to children by nicotine solution. They point out that nicotine solution at a strength used in some refill cartridges can be lethal if ingested (the case they reported was nonfatal).[30]

E-cigarettes may also expose bystanders to emissions, although research in this area is only just beginning. One team of researchers observed increased indoor air levels—albeit less than those associated with tobacco cigarettes—of coarse particulate matter, polycyclic aromatic hydrocarbons, and aluminum following indoor vaping sessions lasting two hours each.[31]

"E-cigarettes do appear to pollute the air, though not as much as conventional cigarettes," Glantz says. "Many of the effects of secondhand smoke on the cardiovascular system have highly nonlinear dose–response curves," he says, so even lower levels of e-cigarette emissions should be taken

Unlike tobacco products, e-cigarettes are not age-restricted. Use among youth approximately doubled between 2011 and 2012, by which time an estimated 1.78 million students in grades 6–12 had tried the devices, according to the Centers for Disease Control and Prevention. © Phanie/Alamy

E-liquids come in hundreds of varieties, many with names and flavors that appear to target youth. Flavors besides menthol are banned from use in conventional cigarettes because they are so effective at easing children into tobacco use. © AP Photo/Reed Saxon

seriously. He adds, "We now have much cleaner indoor air [as a result of widespread bans on public smoking], so I can't see why you would want to re-introduce polluted air with e-cigarettes."

Interim Advice

Many questions remain about whether e-cigarettes are actually safe or simply less harmful than tobacco cigarettes, and debate rages about whether or how the devices should be regulated.[32] But the ongoing uncertainty hasn't appeared to dampen their popularity.

Although researchers are still waiting on data about long-term health effects from e-cigarettes, Crotty Alexander has begun to provide some advice on the devices to her patients. "I don't like to use the word 'safe' with e-cigarettes," she says, "but I do tell my patients that they might be better off if they switched from regular cigarettes to e-cigarettes."

For their part, Glantz and colleagues advise health care providers to read between the lines when a patient asks about e-cigarettes. "A patient who asks a clinician about using the e-cigarette for quitting smoking may be signaling readiness to quit smoking," they wrote in a May 2014 clinicians' brief.[33] "It is most important to support the patient's quit attempt and to try to ensure that any advice given does not undermine the patient's motivation to quit smoking."

Carrie Arnold is a freelance science writer living in Virginia. Her work has appeared in *Scientific American*, *Discover*, *New Scientist*, *Smithsonian*, and more.

REFERENCES

1. See for instance USAcig, Inc. The Electric Cigarette: FAQ's. Temecula, CA:USAcig, Inc. (2014). Available: http://www.usacig.com/faq.aspx [accessed 20 August 2014].
2. Goniewicz ML, et al. Nicotine levels in electronic cigarettes. Nicotine Tob Res 15(1):158–166 (2013); doi: 10.1093/ntr/nts103.
3. Etter J-F, et al. Analysis of refill liquids for electronic cigarettes. Addiction 108(9):1671–1679 (2013); doi: 10.1111/add.12235.
4. Goniewicz ML, et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tob Control 23(2):133–139 (2014); doi: 10.1136/tobaccocontrol-2012-050859.
5. Xu J. QuickStats: number of deaths from 10 leading causes—National Vital Statistics System, United States, 2010. MMWR Morb Mortal Wkly Rep 62(08):155 (2013); http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6208a8.htm?s_cid=mm6208a8_w.
6. Office of the Surgeon General. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Rockville, MD:Office of the Surgeon General, Public Health Service, U.S. Department of Health and Human Services (2014). Available: http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf [accessed 20 August 2014].
7. van Dulken S. The patents for e-cigarettes [weblog entry]. The Patent Search Blog (26 January 2014). Available: http://goo.gl/gYFc87 [accessed 20 August 2014].
8. Regan AK, et al. Electronic nicotine delivery systems: adult use and awareness of the 'e-cigarette' in the USA. Tob Control 22(1):19–23 (2013); doi: 10.1136/tobaccocontrol-2011-050044.
9. Grana R, et al. E-cigarettes: a scientific review. Circulation 129(19):1972–1986 (2014); doi: 10.1161/CIRCULATIONAHA.114.007667.
10. Pearson JL, et al. e-Cigarette awareness, use, and harm perceptions in US adults. Am J Public Health 102(9):1758–1766 (2012); doi: 10.2105/AJPH.2011.300526.
11. Durban R, et al. Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth. Washington, DC:U.S. Congress (14 April 2014). Available: http://goo.gl/pQnBnA [accessed 20 August 2014].
12. FDA. Tobacco Products: General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2), December 2009 [website]. Silver Spring, MD:U.S. Food and Drug Administration (updated 1 July 2013). Available: http://goo.gl/OlJYw6 [accessed 20 August 2014].
13. Corey C, et al. Notes from the field: electronic cigarette use among middle and high school students—United States, 2011–2012. MMWR Morb Mortal Wkly Rep 62(35):729 (2013); http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm.
14. Grana R, et al. Background Paper on E-cigarettes (Electronic Nicotine Delivery Systems). San Francisco, CA:Center for Tobacco Control Research and Education, University of California, San Francisco (December 2013). Available: http://pvw.escholarship.org/uc/item/13p2b72n [accessed 20 August 2014].
15. Dockrell M, et al. E-cigarettes: prevalence and attitudes in Great Britain. Nicotine Tob Res 15(10):1737–1744 (2013); doi: 10.1093/ntr/ntt057.
16. Kleinstreuer C, Feng Y. Lung deposition analyses of inhaled toxic aerosols in conventional and less harmful cigarette smoke: a review. Int J Environ Res Public Health 10(9):4454–4485 (2013); doi: 10.3390/ijerph10094454.
17. Hadwiger ME, et al. Identification of amino-tadalafil and rimonabant in electronic cigarette products using high pressure liquid chromatography with diode array and tandem mass spectrometric detection. J Chromatogr A 1217(48):7547–7555 (2010); doi: 10.1016/j.chroma.2010.10.018.
18. Trehy ML, et al. Analysis of electronic cigarette cartridges, refill solutions, and smoke for nicotine and nicotine related impurities. J Liq Chromatogr Relat Technol 34(14):1442–1458 (2011); doi: 10.1080/10826076.2011.572213.
19. Cameron JM, et al. Variable and potentially fatal amounts of nicotine in e-cigarette nicotine solutions. Tob Control 23(1):77–78 (2014); doi: 10.1136/tobaccocontrol-2012-050604.
20. Goniewicz ML, et al. Nicotine content of electronic cigarettes, its release in vapour and its consistency across batches: regulatory implications. Addiction 109(3):500–507 (2014); doi: 10.1111/add.12410.
21. Sciencelab.com, Inc. Material Safety Data Sheet: Dowfrost MSDS. Houston, TX:Sciencelab.com, Inc. (updated 21 May 2013). Available: http://www.sciencelab.com/msds.php?msdsId=9925835 [accessed 20 August 2014].
22. Dow Chemical Company. Product Safety Assessment (PSA): Propylene Glycol [website]. Midland, MI:Dow Chemical Company (2014). Available: http://www.dow.com/productsafety/finder/prog.htm#HealthInfo [accessed 20 August 2014].
23. Kosmider L, et al. Carbonyl compounds in electronic cigarette vapors—effects of nicotine solvent and battery output voltage. Nicotine Tob Res; doi: 10.1093/ntr/ntu078 [online 15 May 2014].
24. FDA. Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA [website]. Silver Spring, MD:U.S. Food and Drug Administration (updated 22 April 2014). Available: http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm [accessed 20 August 2014].
25. Vasundhra B, et al. Comparison of electronic cigarette refill fluid cytotoxicity using embryonic and adult models. Reprod Toxicol 34(4):529–537 (2012); doi: 10.1016/j.reprotox.2012.08.001.
26. Keith CH, Derrick JC. Measurement of the particle size distribution and concentration of cigarette smoke by the "conifuge." J Colloid Sci 15(4):340–356 (1960): doi: 10.1016/0095-8522(60)90037-4.
27. Williams M, et al. Metal and silicate particles including nanoparticles are present in electronic cigarette cartomizer fluid and aerosol. PLoS ONE 8(3):e57987 (2013); doi: 10.1371/journal.pone.0057987.
28. Hua M, et al. Health-related effects reported by electronic cigarette users in online forums. J Med Internet Res 15(4):e59 (2013); doi: 10.2196/jmir.2324.
29. Chatham-Stephens K, et al. Notes from the field: calls to poison centers for exposures to electronic cigarettes—United States, September 2010–February 2014. MMWR Morb Mortal Wkly Rep 63(13):292–293 (2014); http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm.
30. Bassett RA, et al. Nicotine poisoning in an infant. N Engl J Med 370(23):2249–2250 (2014); doi: 10.1056/NEJMc1403843.
31. Schober W, et al. Use of electronic cigarettes (e-cigarettes) impairs indoor air quality and increases FeNO levels of e-cigarette consumers. Int J Hyg Environ Health 217(6):628–637 (2013); doi: 10.1016/j.ijheh.2013.11.003.
32. FDA. Tobacco Products. Deeming—Extending Authorities to Additional Tobacco Products [website]. Silver Spring, MD:U.S. Food and Drug Administration (updated 11 August 2014). Available: http://www.fda.gov/TobaccoProducts/Labeling/ucm388395.htm [accessed 20 August 2014].
33. Grana R, et al. Cardiology patient page: electronic cigarettes. Circulation 129(19):e490–e492 (2014); doi: 10.1161/CIRCULATIONAHA.114.008545.

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Erratum: "Vaping and Health: What Do We Know about E-Cigarettes?"

The September 2014 News article "Vaping and Health: What Do We Know about E-Cigarettes?" [Environ Health Perspect 122:A244–A249 (2014); http://dx.doi.org/10.1289/ehp.122-A244] has been revised to correct errors and clarify certain statements. The article incorrectly referred twice to e-cigarette emissions as "secondhand smoke." However, e-cigarettes do not produce smoke; they produce vapor. In addition, "Advertisements claim e-cigarettes offer health benefits by helping smokers quit" should have been attributed to reference 1, and reference 1 itself should have indicated that the cited marketing statements were provided as an example. Finally, the statement "One team of researchers observed increased levels—albeit less than those associated with tobacco cigarettes—of coarse particulate matter, polycyclic aromatic hydrocarbons, and aluminum following indoor vaping sessions lasting two hours each" should have specified that researchers observed these increased levels *in indoor air*.

EHP regrets the errors.

Placer County bans e-cigarettes from public buildings and vehicles

BY RICHARD CHANG - RCHANG@SACBEE.COM

03/10/2015 1:14 PM | Updated: 03/10/2015 9:47 PM

Cory Parravano, left, manager of The Vapor Spot on J Street in midtown Sacramento talks to customers who smoke e-cigarettes on Wednesday, Jan. 27, 2015 in Sacramento, Calif. Placer County on Tuesday banned vaping from public buildings and vehicles. RANDY PENCH RPENCH@SACBEE.COM

Story Comments

Placer County on Tuesday became the latest jurisdiction in the Sacramento region to restrict electronic cigarettes.

The Board of Supervisors voted unanimously to outlaw the use of electronic cigarettes, also known as "vaping," within public buildings and inside county-owned vehicles. The ordinance will take effect in late April.

In recent years, vaping has gained a strong following among youths and has been touted by supporters as a safe alternative to traditional tobacco products such as cigarettes. But public health officials have said the chemicals contained in e-cigarettes are anything but safe.

The Placer County measure passed with little fanfare Tuesday morning, with no one speaking about the issue during public comment.

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by Sen. Mark Leno would put major restrictions -cigs

're out, tobacco: Bill would ban products at all fornia baseball venues

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would raise California smoking age to 21

y's curbs tobacco sales, citing health concerns

Kirk Uhler, chairman of the Board of Supervisors, called it a logical extension of trying to create a comfortable work environment for employees.

"We had heard enough feedback from folks about not having that activity in the workplace," Uhler said.

It is unclear how popular e-cigarettes were among county employees. Michael Romero, a program supervisor in Placer's Public Health division, said there was "anecdotal evidence" that vaping was occurring in county facilities, but he could not quantify the number of workers affected.

Romero said the measure will protect county employees and the public until more is known about the effects of e-cigarette vapors.

E-cigarettes operate much like traditional cigarettes. Instead of tobacco, they are filled with a type of flavored juice that is heated through the battery-powered device. Nicotine also can be added if desired. Users then inhale the vaporized liquid.

According to the California Department of Public Health, electronic cigarettes contain at least 10 chemicals known to cause cancer or birth defects. In a January report about vaping, the Public Health department said, "there is no scientific evidence that e-cigarettes help smokers successfully quit traditional cigarettes."

Robert Beadle, a vaping consultant for several smoke shops in Placer County, was supportive of the county's decision but emphasized there isn't yet any proof that vaping is harmful.

"If you weigh it out between smoking and vaping," he said, "vaping will win every single time."

Vaping, for example, doesn't produce a combustible flame, nor is there the trash of cigarette butts, Beadle said.

However, momentum has been building against the industry.

In January, state Sen. Mark Leno, D-San Francisco, proposed legislation that would ban vaping in bars, restaurants, hospitals and other workplaces. Days later, California's top health officials launched a campaign to educate the public about the dangers of vaping.

Neither Sacramento County nor the city of Sacramento has vaping bans on the book.

But Sacramento County spokeswoman Chris Andis said there have been informal conversations about pursuing such an ordinance.

More than 150 jurisdictions in California have passed legislation regulating e-cigarettes, according to the American Lung Association, including the cities of Davis, Folsom, Rancho Cordova and Woodland.

Call The Bee's Richard Chang at (916) 321-1018. Follow him on Twitter @RichardYChang.

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