

The State of Tobacco Control in Maryland: A Look Back and Ahead



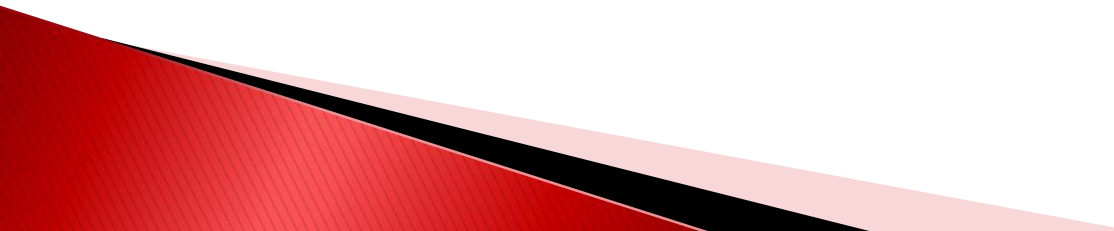
The Healthy St. Mary's Partnership Annual Meeting
November 17, 2016

Center Profile

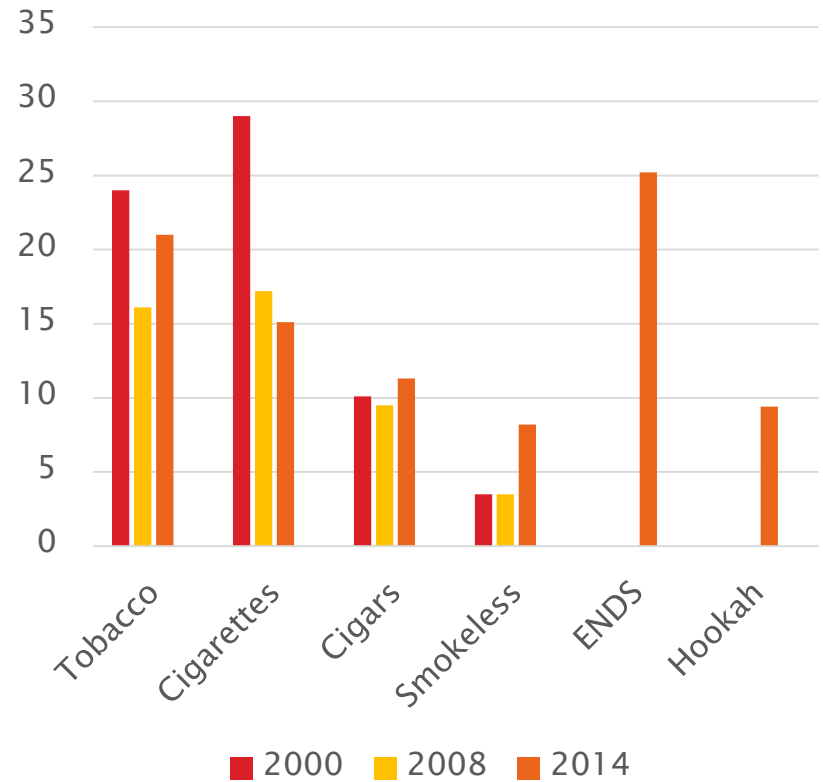
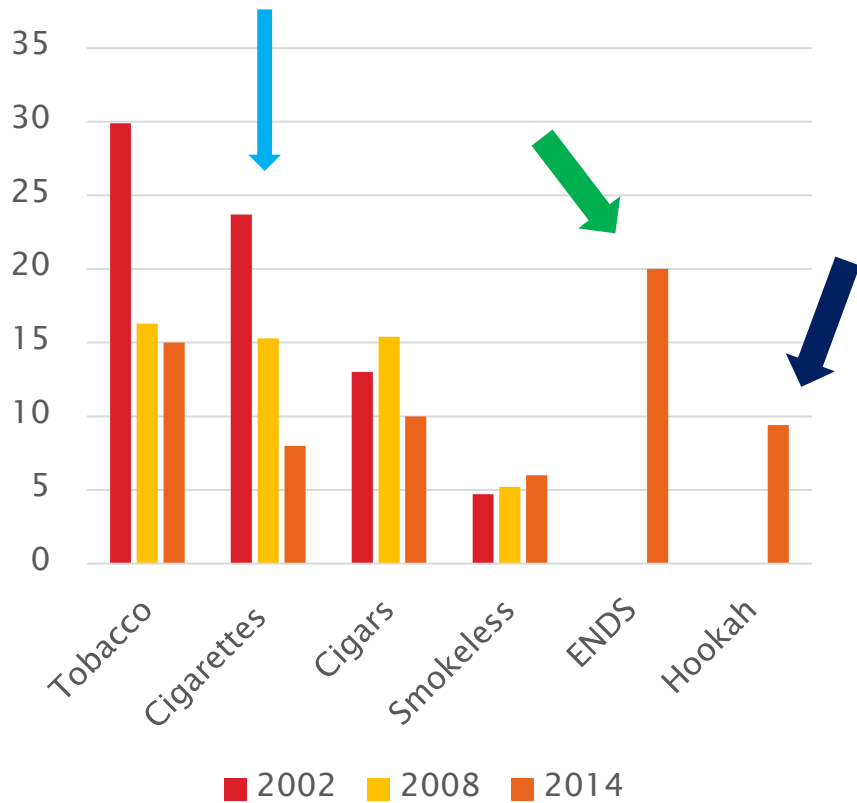
- ▶ Founded in 2001
- ▶ Partnership between UM School of Law, DHMH, and Maryland Office of the Attorney General
- ▶ CDC/DHMH grant-funded legal center
- ▶ *Pro bono* legal assistance to:
 - Legislators
 - Health officials
 - Gov't Attorneys
 - NGOs
 - Individual Citizens



Presentation Overview

- ▶ **Youth Tobacco Use: Then and Now**
 - ▶ **Emerging Products**
 - ▶ **FDA “Deeming” Rule**
 - ▶ **State and Local Action**
 - ▶ **What to Look for in 2017?**
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Maryland High School Students 2002-2014



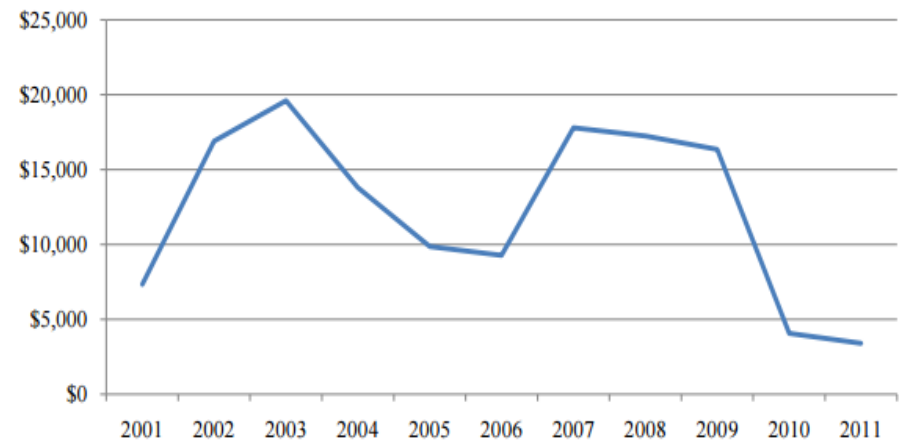
MARYLAND

ST. MARY'S

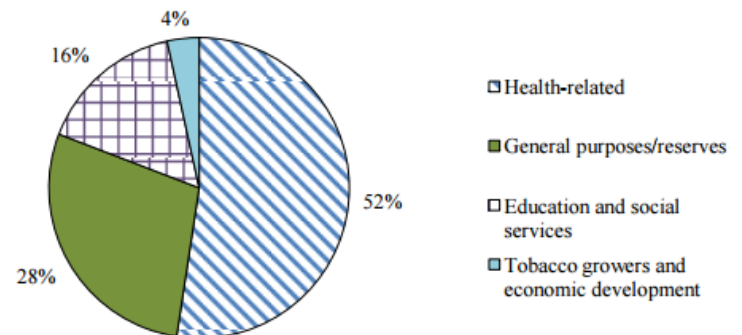
So What Happened?

- ▶ The State spent money to prevent youth initiation and reduce use
- ▶ In 2000, General Assembly created the Cigarette Restitution Fund with money from 1998 Master Tobacco Settlement Agreement
 - Peak - \$210 million (2002)
 - Median - \$150 million
 - Low - \$110 million (2006)
- ▶ Administered by DHMH
 - 2002 - \$17 million
 - 2008 - \$16 million
 - 2014 - \$10 million

Exhibit 8
Funding for Tobacco Use Prevention and Cessation
Fiscal 2001-2011
(\$ in Thousands)



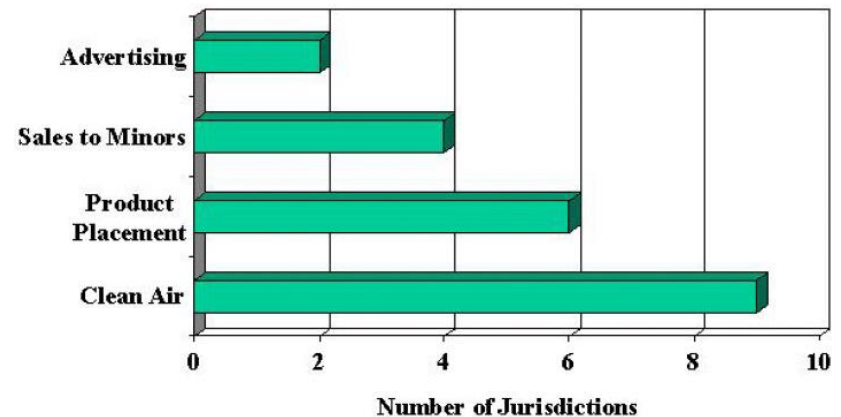
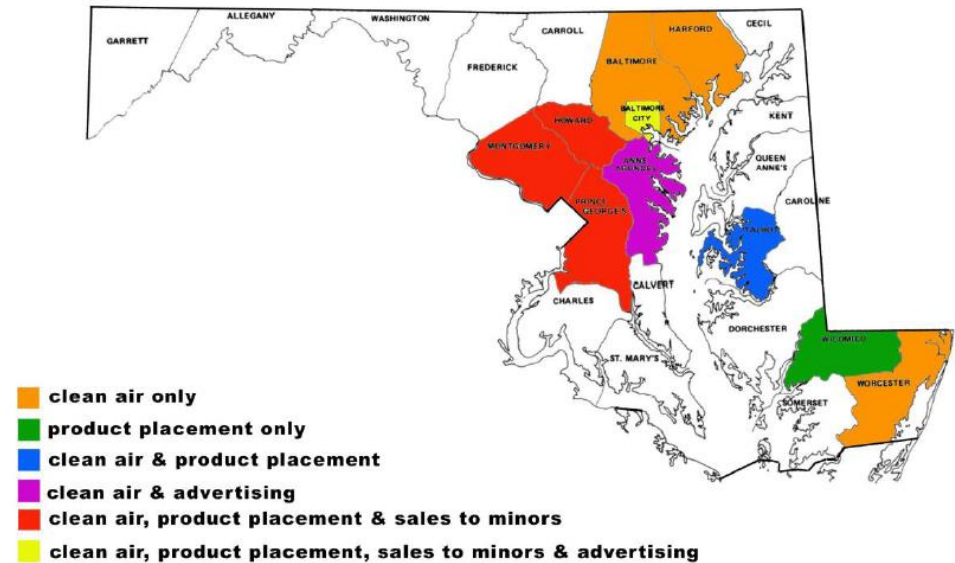
Source: Department of Budget and Management



Legislative Changes

- ▶ Cigarette Excise Tax
 - 2002 - \$.66 → \$1.00
 - 2008 - \$1.00 → \$2.00
- ▶ Clean Indoor Air
- ▶ Fire Safe Cigarettes
- ▶ OTP Excise Tax
 - 2012 – Cigars: 15% → 30%;
 - 2012 – Smokeless: 15% → 70%
- ▶ OTP Licensing
- ▶ E-Cigarette Sales to Minors
- ▶ County and Municipal laws:
 - Civil Enforcement
 - Product Placement
 - Indoor Air

2002



Emerging Products

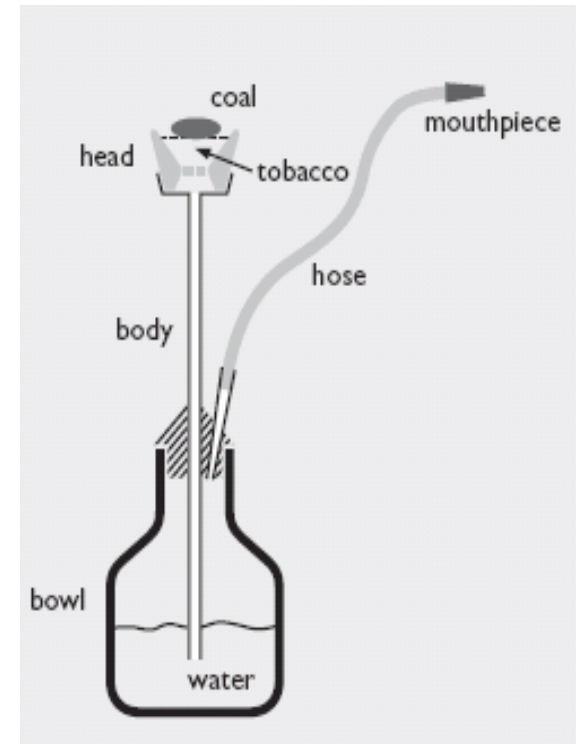
PROBLEM:

E-CIGARETTES AND
HOOKAHS ARE GAINING
POPULARITY AMONG
STUDENTS.



Hookah

- ▶ A *hookah* is a single or a multi-stemmed instrument used to smoke tobacco, typically in a communal setting.
- ▶ Design and size vary, but generally consist of:
 - (1) a bowl where tobacco is heated with charcoal;
 - (2) a body whose chamber holds water;
 - (3) a flexible hose leading from the body; and
 - (4) a mouthpiece through which smoke is drawn from the chamber.
- ▶ *Shisha* is the moist, sticky tobacco smoked in hookah; it is often soaked in honey, fruit, or other flavor components.
- ▶ Available flavors include apple, banana, cappuccino, lemon, orange, papaya, piña colada, raspberry, rose, and strawberry.
- ▶ One bowl of shisha can last up to 45 minutes, and including rental of the hookah can cost around \$10-\$15 per use.



Health Effects

- ▶ Smoke inhaled in an average hookah smoking session of 45 minutes is *about 150 times that of one cigarette.*
- ▶ The charcoal used to heat the tobacco can raise health risks by producing high levels of carbon monoxide, metals, and cancer-causing chemicals
- ▶ Hookah use is associated with *lung cancer, respiratory illness, low birth-weight, and periodontal disease.*
- ▶ Shared mouthpieces *increase risks of spreading communicable diseases* like tuberculosis, hepatitis, and herpes, and more common viruses like the flu.



E-Cigarettes (ENDS)

- ▶ Battery-operated device containing liquid nicotine that is aerosolized and inhaled by the user
- ▶ May be sold by any retailer – no specific license required
- ▶ “E-cigarettes have the potential for harm and benefit to the public’s health. It is important to consider their effects on specific populations, including youth, pregnant women, and adult smokers.” – CDC
- ▶ “While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals present pose limited danger, remains valid. The current best estimate is that e-cigarette use is around 95% less harmful to health than smoking” – Public Health England



E-Cigarette Market in 2016: Current Sales and Future Projections

▶ Sales Growth 2010-2014

- Average annual growth rate: **114%**
- Annual Sales:
 - 2010 - **\$82 million**
 - 2011 - **\$195 million**
 - 2012 - **\$500 million**
 - 2013 - **\$1.7 billion**
 - 2014 - **\$2.5 billion**
 - 2015 - **\$3.3 billion**

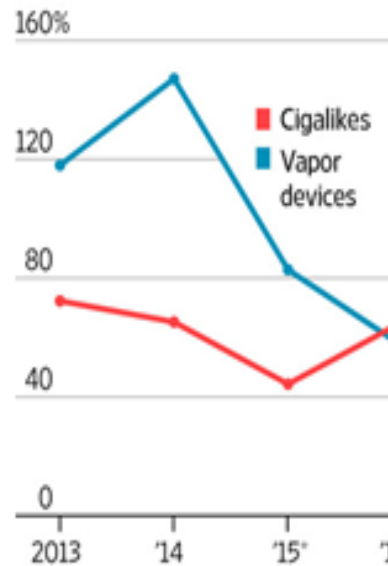
▶ Market Slowdown 2015

- Growth rate cut in half (114% to 57%)
- Sales of “cigalikes” rapidly declining

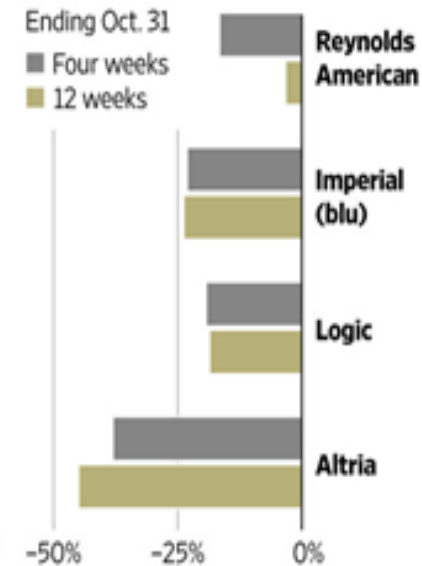
Out of Juice

Sales of e-cigarette devices like cigalikes and vaporizers are slowing down considerably this year.

Change from a year earlier in sales



Top companies, change from a year earlier in e-cigarette sales



*Forecast Sources: Euromonitor (overall sales); Nielsen, Wells Fargo (top companies)

THE WALL STREET JOURNAL.

Blip or Trend?

“Consumers are disenchanted right now with these products. It’s not that different from diet soda, e-cigs need to mimic cigarettes or users won’t switch.”

– Bonnie Herzog, Senior Analyst, Wells Fargo

- Revenue declined for **4 straight months** to end 2015 (first time ever)
 - Total sales eclipsed 2014, but were **\$200 million** below estimates
 - Conflicting health and safety data and regulatory uncertainty blamed for declining sales
 - Total Revenue 2023 (projected) - \$21.6 billion
- ▶ **Changing landscape: “Cigalikes” vs. Personal Vaporizers**
 - Cigalikes: **\$1.4 billion**
 - Vaporizers: **\$1.9 billion**
 - ▶ **Independent Manufacturers vs. Tobacco Manufacturers**
 - **Industry % of market:**
 - 2013 – 32%
 - 2015 – 48%
 - **2023 (projected) – 75%**
 - **Industry Total Revenue:**
 - 2013 - \$.2 billion
 - 2015 - \$.8 billion
 - **2023 (projected) – \$16 billion**

Shifting Retail Market

2008 to 2013 - “Cigalike” sales made up majority of the U.S. market

2014 – “Open systems” or vaporizers surpass cigalikes; account for 60% of overall market

2015 - U.S. Market Sales:

- ▶ **Mass Retail Stores** (convenience, grocery, etc.)
 - Cigalikes – \$600 million
 - Vaporizers - \$300 million
- ▶ **Online**
 - Cigalikes - \$800 million
 - Vaporizers - \$400 million
- ▶ **Vape Shops**
 - Cigalikes - \$400 million
 - **Vaporizers - \$1.2 billion**



Who's Using ENDS?

▶ Youth

- From 2011 to 2015, e-cig use among high school students *increased from 2% to 16%*
- In 2014, e-cigarettes (16%) became the *most commonly used tobacco product* among middle and high school students, *outpacing cigarettes (9.3%), cigars (8.6%) and smokeless (6.0%)*
- Estimated *19%* of high school males and *17.2%* of non-Hispanic whites reported current use

▶ Adults

- *3.7%* of adults *use* e-cigarettes, and *12.6%* *have ever used*
- *22%* of former smokers *use* and *55.4%* of former smokers *have ever used*
- *15.9%* of current smokers use and *47.6%* *have ever used*
- Current/former smokers trying to quit were most likely group to use e-cigarettes

Who's Using Hookah?

- ▶ During 2011–2015, substantial increases were observed in e-cigarette and hookah use among high school and middle school students
 - *4.1% → 9.4% of high school students*
 - *1% → 2% of middle school students*
- ▶ Among high school seniors in the United States, about 1 in 5 boys (17%) and 1 in 6 girls (15%) had used a hookah in the past year
- ▶ Other small studies of young adults have found high prevalence of hookah use among college students; past-year use ranging from *22% to 40%*

Why Hookah and ENDS?

- ▶ Cheap – low or no excise taxes
- ▶ Absence of:
 - Education
 - Research
 - Regulation
 - Indoor use
 - Advertising
 - Licensing
 - Product Placement
 - Health Warnings
 - Free Samples
 - Sales restrictions (i.e. flavor bans)



Federal Regulation of Emerging Products



Drug-Device or Tobacco Product?

Sottera, Inc. v. FDA (2010)

- **April 2009** – FDA denies entry of NJOY and Smoking Everywhere e-cigarettes into the U.S. on the grounds that they were unapproved drug-device combinations under the federal Food, Drug and Cosmetic Act.
- Sottera (NJOY) and Smoking Everywhere bring suit arguing e-cigarettes are not drug-devices but tobacco products since the liquid nicotine is derived from tobacco
- **Result**: Court held that FDA lacked authority to regulate e-cigarettes as drug-devices absent therapeutic claims (i.e. helps people quit smoking)

So, if FDA is going to regulate e-cigarettes they **MUST** do so within their tobacco products authority...

Deeming Regulation

- ▶ The Tobacco Control Act (2009) granted FDA authority over the manufacture, marketing and sale of tobacco products
- ▶ The Act directly regulated cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco
- ▶ FDA authorized to “deem” any “product made or derived from tobacco that is intended for human use” as a tobacco product and subject to all or part of the Act
- ▶ On *April 24, 2014* FDA issued the Notice of Proposed Rulemaking (NPRM) that “deems” anything meeting the statutory definition of a tobacco product, including ENDS as subject to the Tobacco Control Act; comment period closed *August 8, 2014*
- ▶ May 2016 – FDA issues final rule extending tobacco control authority to ENDS, hookah/shisha, and other tobacco products *effective August 8, 2016*

What will “Deeming” Mean for ENDS and Hookah?

- **Automatic Requirements** – any deemed tobacco product must:
 - Register with FDA and report product and ingredient listings;
 - Not make reduced risk claims without scientific data and FDA approval
 - Not distribute free samples
 - Pay user fees (CTP is user fee funded, not taxpayer funded)
 - Pre-market review of all products marketed after February 15, 2007*
- **Non-Automatic Requirements**
 - Minimum Age (18) and ID check requirements
 - Health warnings on packaging
 - Vending machine sales prohibited (unless in 18+ facility)

Child-Resistant Packaging

Child Nicotine Poisoning Prevention Act of 2015

- ▶ Any “liquid nicotine container” must meet federal “special packaging” standard
 - Significantly difficult for children under 5 to open, but not difficult for adults to use properly
 - 80 percent of children tested must not open the package within 10 minutes; 90 percent of adults tested are able to open properly in under 5 minutes, and within 1 minute in a second test
- ▶ Excludes “sealed, pre-filled, and disposable” e-liquid containers **IF** inaccessible through customary use
- ▶ FDA may still regulate child-resistant packaging
- ▶ Enforcement
 - CPSC may levy civil money penalties, seize products, enjoin import or sale
 - State Attorneys General may bring suit and enjoin for violation of the Act
- ▶ Effective July 26, 2016

Lawsuits

- ▶ *Nicopure Labs, LLC v. FDA*
- ▶ *Lost Art Liquids, LLC v. FDA*
- ▶ *Cyclops Vapor 2 v. FDA*

Arguments:

- ▶ FDA definition of “tobacco product” exceeds statutory authority
- ▶ Refusal to alter “grandfather date” is arbitrary and capricious
- ▶ Free sample ban violates 1st Amendment
- ▶ Inadequate cost-benefit analysis



Recap

On the books now, or in the coming months, are the following:

- ▶ Sales to minors (state and federal)
- ▶ Child-resistant packaging
- ▶ ID Check
- ▶ Vending Machine Sales
- ▶ Health Warnings

So, what regulatory gaps are left for state and local governments?



Maryland State Laws

ENDS

- ▶ Sales to Minors
 - Health-General Article, § 24-305

Hookah

- ▶ Indoor Use (for products containing tobacco)
- ▶ Taxation → 30% of wholesale
- ▶ Sales to Minors
 - Criminal Law Article, § 10-107
- ▶ Retail License (OTP)

IT'S THE LAW.

NO CIGARETTES

NO CIGARS

NoTobaccoSalesToMinors.com

NO SPIT TOBACCO

NO E-CIGARETTES

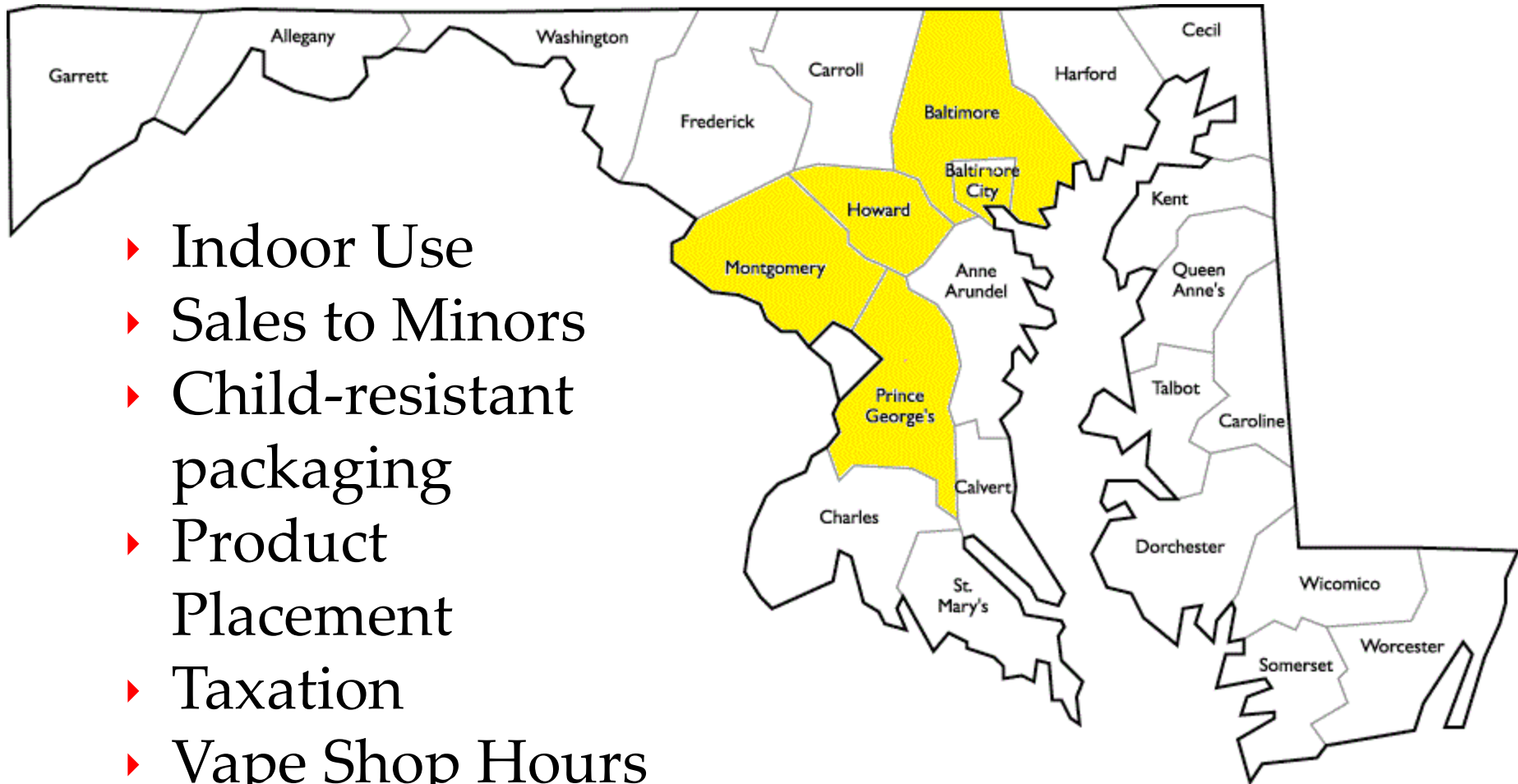
RETAILERS MUST ASK FOR PHOTO I.D.
FROM EVERYONE UNDER 27.

UNDER 18? NO TOBACCO.

CHECK I.D.
We Don't Sell Tobacco to Kids

MARYLAND
Department of Health and Mental Hygiene

Local ENDS Regulation in Maryland

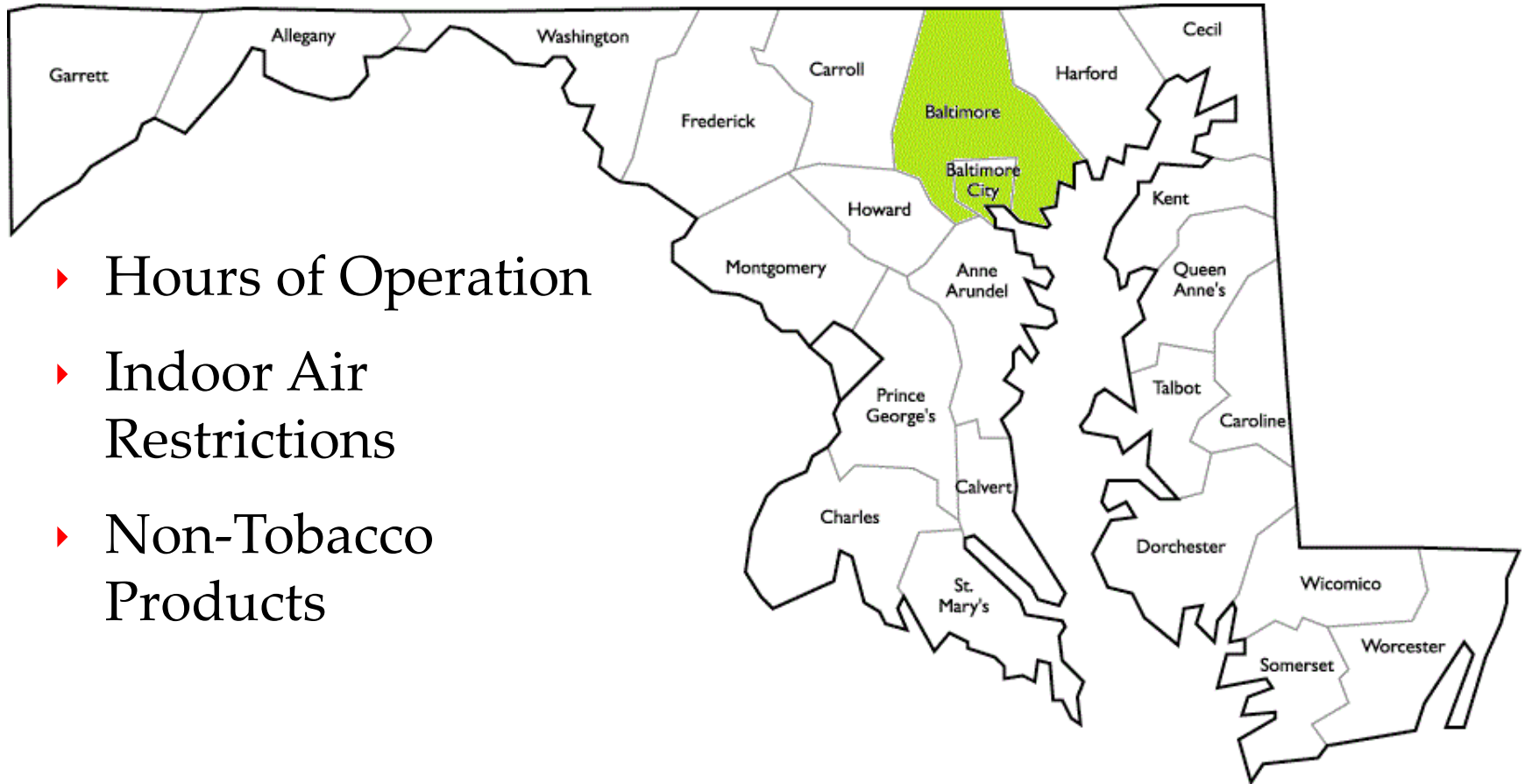


- ▶ Indoor Use
- ▶ Sales to Minors
- ▶ Child-resistant packaging
- ▶ Product Placement
- ▶ Taxation
- ▶ Vape Shop Hours

Impact of Local Regulation

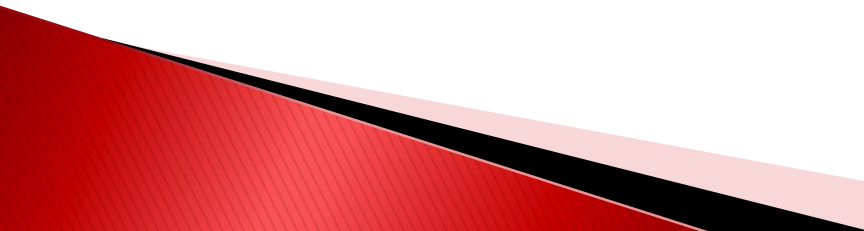
- ▶ Current ENDS Use Rates (Out of 22):
 - Baltimore City (20th)
 - Baltimore County (18th)
 - Howard (21st)
 - Montgomery (19th)
 - Prince George's (22nd)
- ▶ Montgomery County Tax – Estimated \$300K for 2016 (originally projected to exceed \$2 million)
- ▶ No good data on legislative impact, but Surgeon General and IOM highlight effective tobacco control policies:
 - Taxation
 - Indoor Air Restrictions
 - Youth Access Restrictions/Comprehensive Enforcement
 - Education/Mass Media

Local Hookah Regulation in Maryland



- ▶ Hours of Operation
- ▶ Indoor Air Restrictions
- ▶ Non-Tobacco Products

Impact of Local Regulation

- ▶ Significant reduction in late night/early morning calls to law enforcement (disturbances/violence)
 - ▶ Restricting hookah hours of operation to 6 AM to 12 AM reduced business up to 90% at one establishment
 - ▶ Hookah bars have exploded in Baltimore City despite stringent indoor air restrictions
 - ▶ High volume of calls to law enforcement at/near hookah bars
- 

**What's ahead for Maryland
tobacco control?**



Expected Legislation

- ▶ Tobacco Control Funding
- ▶ ENDS Licensing
- ▶ Tobacco 21
- ▶ Statewide Civil Enforcement
- ▶ Indoor Air



General Assembly
of Maryland

Questions?



Presenter Information

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