

Key Public Health Initiatives: A Year in Review

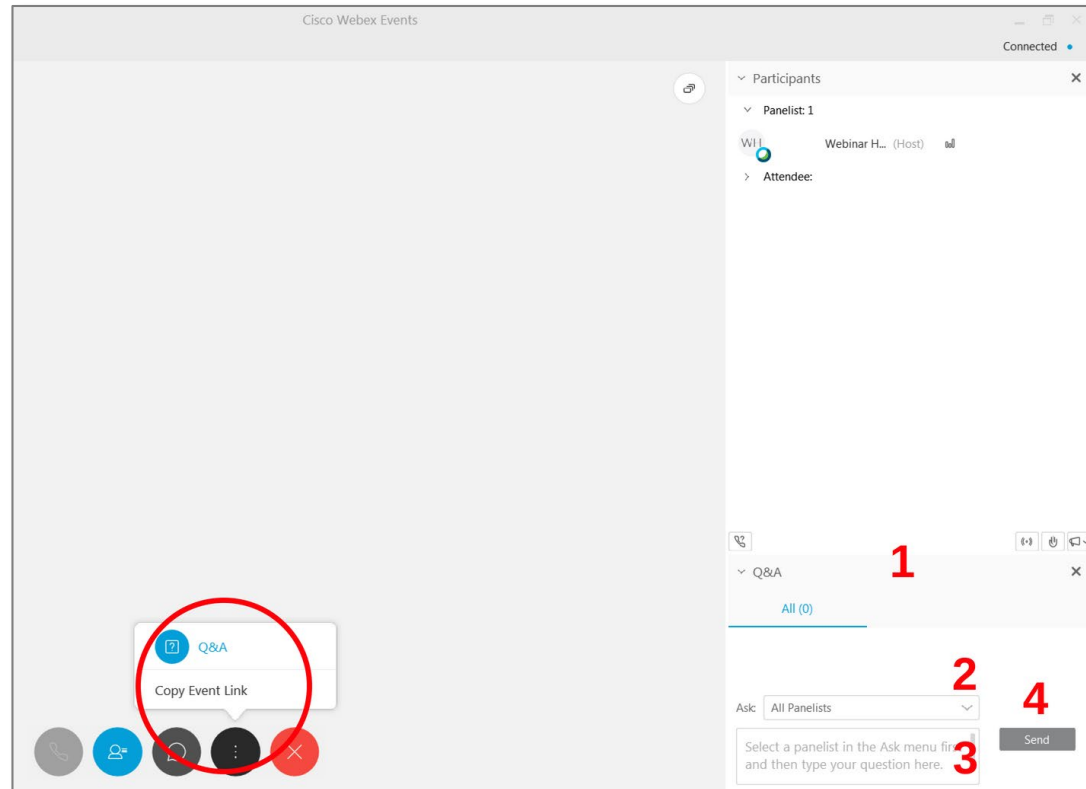
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- J.D., University of Maryland
- Research interests/areas of expertise:
 - Injury Prevention and Safety
 - Tobacco Control
 - Environmental Public Health
 - Food Safety
 - Oral Health

Presenter



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 - Scope of practice
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 - Medical Cannabis Regulation
 - Environmental Health
 - Telehealth/Broadband Access
 - Health Equity

Key Public Health Initiatives: A Year in Review

Scope of Practice

Mellissa Sager, JD

Network for Public Health Law – Eastern Region

December 13, 2018

What is Scope of Practice?

- A health care provider's scope of practice describes the procedures, actions and processes that a health care practitioner is permitted to undertake in keeping with the terms of his or her professional license.
- Laws, licensing bodies, and regulations establish a provider's scope of practice.
- Provisions are tied to the education, training, experience, and special qualifications of a provider.
- Originally designed to protect the public.
- Providers, both physicians and non-physicians, have a financial interest in SOP laws.

Common Restrictions Placed on Providers:

- Supervision Requirements
- Collaborative Practice Agreements (CPAs)
- Prescribing Limitations
- Location Restrictions
- Hospital / Admitting Privileges
- Referral Requirements

Public Health Implications:

- Almost 20 percent of Americans, or more than 40 million adults, can't afford or access needed health care.
- Some residents in rural areas have to drive over 100 miles to access care.
- Due to federal health care reform, demand for care has increased, bringing millions of new patients into the market.
- The US will need to hire 2.3 million new health care workers by 2025 in order to adequately meet the needs of patients.
- Those who are unable to obtain primary care may develop more serious illnesses and seek treatment in hospital emergency rooms, which results in longer waiting times for other patients and higher health care costs.

Why Scope of Practice Changes Can Help:

Allowing providers to practice to the full extent of their education and training can increase access to and decreases the costs of medical care. Non-physician and non-dentist providers are trained and prepared to undertake greater responsibilities to meet the needs of the health care system.



Pharmacists:

- Pharmacy practice has expanded to include much more than dispensing medications.
- Trained in “disease management” of chronic conditions such as diabetes and heart conditions and other services, such as administering vaccines.
- Skilled in recognizing the potential for unwanted adverse interactions between a patient’s medications and counseling patients on how to properly take medications.
- Some state SOP laws allow pharmacists to engage in disease management or administer flu shots and other states do not. Some states allow pharmacists to adjust/substitute and even prescribe medications as well as order and interpret lab tests; others do not.

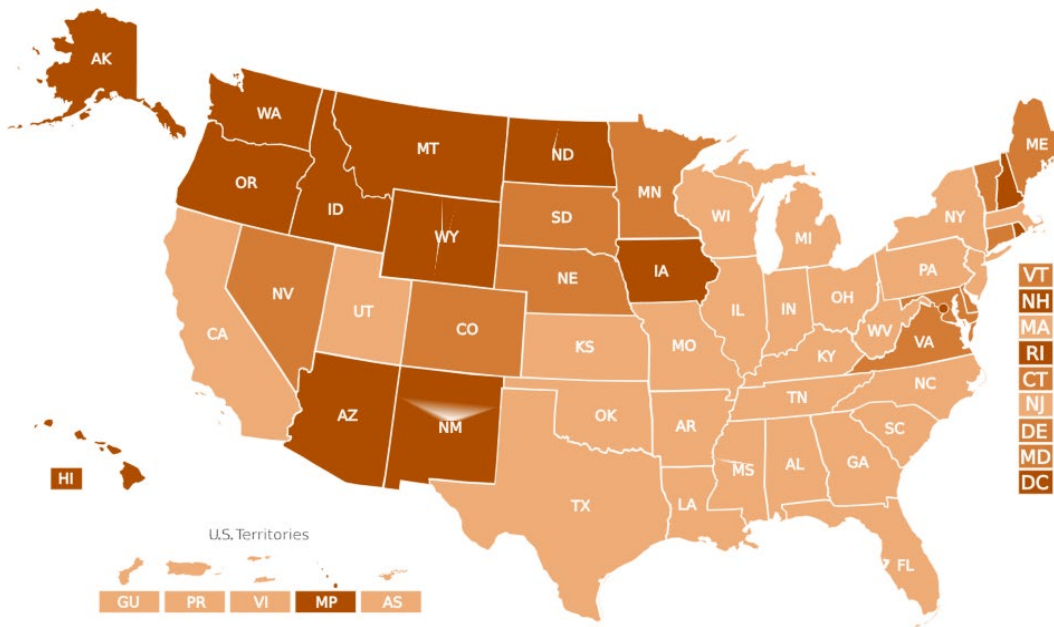
Dental Hygienists and Dental Therapists:

- Dental hygienists and dental therapists practice in private settings, community-based clinics and rural areas. They practice under varying levels of supervision by dentists, allowing these providers to meet needs in nontraditional, tribal, school based and community settings.
- Some states allow dental hygienists to go to long-term care facilities, public dental clinics and schools, away from the direct supervision of a dentist, to clean teeth. But many states do not.
- Dental therapists typically provide many of the same services as dental hygienists, such as cleaning teeth and taking X-rays but may also provide fillings, replace crowns and perform extractions of baby teeth. Dental therapists typically work with uninsured, low-income and underserved populations to help them get necessary dental care
- Dental Therapists are currently recognized in five states and two territories. Alaska, Maine, Minnesota, Vermont, Washington, American Samoa and the Northern Mariana Islands.

Nurse Practitioners:

- Nurse practitioners are advanced practice registered professional nurses, prepared through advanced graduate education and clinical training to provide a range of health services.
- Nurse practitioners assess patients, order and interpret diagnostic tests, make diagnoses (common and complex), initiate and manage treatment plans—including prescribing medications.
- Some states include NPs in the definition of a primary care provider, others do not. Many states allow NPs to practice independently, but still some do not. Some states grant NPs full prescribing authority, some do not.

Nurse Practitioners:



Physician relationship required [more info](#)

NPs are required to have a relationship with a physician which outlines procedures the NP is allowed to do and procedures for consulting with the physician. Some states may allow an NP to have a relationship with a hospital, institution or other health care provider.

Transition to independent practice period required [more info](#)

NPs must complete a certain number of practice hours within a regulated relationship with a physician, NP or other health care provider before practicing independently.

Full independent practice authority [more info](#)

NPs evaluate, diagnose, order and integrate diagnostic testing, test, manage and prescribe for patients

Other Considerations:

- Business
- Patient Choice
- Continuity of Care

Conclusions:

- Scope of practice policies need to be evidence-based. Based on demonstrated ability of health care professions to deliver services safely and effectively.
- Professions can and will have overlapping scopes of practice.
- Patient safety and wellness should always be the primary factor when considering SOP policy change and can be addressed through research and evidence.
- Reimbursement policies, insurance practices and regulations, organizational policies, and educational opportunities still serve as barriers to access and require evaluation.



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Key Updates: Vaping and FDA Regulation

Brooke Torton, Deputy Director

The Deeming Rule

- In 2009, the Tobacco Control Act gave the FDA authority over tobacco products and required they adopt certain requirements for ALL tobacco products under its authority.
- This immediate authority extended to cigarettes, cigarette tobacco, roll your own tobacco, and smokeless tobacco.
- The FDA was also given authority to issue future regulations, deeming other products subject to the Act.
- Effective August 8th, 2016, the “Deeming Rule” provides the FDA with authority to regulate new products, most notably, cigars and electronic cigarettes.

The Deeming Rule

- Effective August 8th, 2016, the FDA finalized a rule which regulated all tobacco products, including cigars, pipe tobacco, gels/dissolvables, hookah/shisha, and ENDS (electronic nicotine delivery systems).

Manufacturer Requirements

- Report product and ingredient listings;
- Register with the FDA;
- Report harmful / potentially harmful ingredients;
- Have health warnings on product packages & ads;
- Not make reduced risk claims without scientific data & FDA approval;
- Not use descriptors such as “light”, “low”, and “mild”;
- Not make false or misleading claims in labels or ads;
- Pay user fees (CTP is not taxpayer funded); and
- ***Subject to premarket review***

Retailer Requirements

- Minimum age and ID;
- Vending machine sales prohibited (unless in 18+ facility); and
- Distribution of free samples prohibited

What does “Electronic Cigarette” include?

- These battery-operated products typically heat nicotine, flavor, and other chemicals into an aerosol that the user inhales:
 - Electronic cigarettes, e-hookahs, e-cigars, vape pens, advanced refillable personal vaporizers, electronic pipes.
- Inhaling is referred to as “vaping” or “JUULING.”

Is “JUUL” an Electronic Cigarette?

- Yes. JUUL is an electronic cigarette resembling a USB.
- The liquids in JUUL pods contain nicotine salts which are absorbed into the body at almost the same rate as a combustible cigarette. The vapor is inhaled more smoothly than combustible cigarettes.
- JUUL has more than twice the amount of nicotine as many other brands of e-cigarettes.

More on “JUUL”

- 72% market share of electronic cigarettes
- High school student e-cigarette use increased 78% between 2017 and 2018. It rose 48% among middle school students.
- More than 3.6 million middle and high school students were current (past 30 day) e-cigarette users in 2018, representing a 1.5 million student increase since 2017.

2017 FDA Commissioner Announcements

- On July 28, 2017, the FDA announced a plan to develop regulations lowering the nicotine levels in cigarettes, potentially to non-addictive levels.
- By reducing the addictiveness of cigarettes, users may be more likely to quit and youth less likely to ever begin smoking.
- FDA indicated that **key portions of the "Deeming Rule," as it relates to electronic cigarettes and cigars, will be placed on hold for several years** to provide the FDA with additional time to determine whether and how the provisions related to electronic cigarette manufacturing work together with this proposal.

FDA, September 2018 Announcements

- The FDA announced a series of critical and historic enforcement actions related to the sale and marketing of e-cigarettes to children.
 - 1,300 warning letters and civil money penalty complaints (fines) to retailers who illegally sold e-cigarette products to minors during a nationwide undercover blitz.
 - 135 No-tobacco-sale orders.
- FDA also issued 12 warning letters to online retailers that are selling misleadingly labeled and/or advertised e-liquids resembling kid-friendly food products such as candy and cookies.
- The agency also sent letters to JUUL and several other companies requiring them to submit documents to help FDA better understand the high rates of youth use and appeal.

FDA, September 2018 Announcements

- FDA requested that manufacturers take voluntary actions and meaningful steps to curb youth appeal.
- If they fail to do so, or if the plans do not appropriately address this issue, the FDA will consider revisiting the current policy which allows these products to remain on the market.
- “Let me be clear: Everything is on the table. This includes the resources of our civil and criminal enforcement tools.”
- “If the companies don’t know, or if they don’t want to know, that straw purchases are occurring, we’ll now be helping to identify it for them. If violative activities are found, the FDA has both civil and criminal remedies at its disposal.”

FDA, October 2018 Announcements

- FDA sent letters to 21 e-cigarette companies, seeking information about whether more than 40 products, including some flavored e-cigarette products, are being illegally marketed and outside the agency's current compliance policy.
- Flavors are the “principal drivers” of youth appeal.
- Meeting with Altria Group Inc., JUUL Labs Inc., Reynolds American Inc., Fontem Ventures, and Japan Tobacco International USA Inc.

FDA, November 2018 Announcements

- CDC releases findings from the National Youth Tobacco Survey.
 - 3.6 million middle and high school students were current (past 30 day) e-cigarette users in 2018, up from 1.5 million students in 2017.
 - 78 percent increase in high school students (now 20.8%) and 48% increase in middle school students (4.9%)
 - Youth are using more frequently: in 2017, 20% of youth were using the product on 20 or more of the last 30 days, now it has risen to 27.7 %.
 - Significant increase in current flavored e-cigarette use: 2017: 60.9%; 2018: 67.8 %.

FDA, November 2018 Announcements

- Revisit compliance policy as it relates to all flavored ENDS products (other than tobacco, mint and menthol flavors or non-flavored products) that are not sold in age-restricted, in-person locations;
- Revisit compliance policy on flavored cigars;
- Ban menthol in combustible tobacco products (cigarettes and cigars); and
- Removal of products marketed toward children.

JUUL Lawsuits

- JUUL created by Pax Labs
- Current Lawsuits
 - Colgate v. JUUL Labs
 - D.P. v. JUUL Labs and Pax Labs
 - Cooper v. JUUL Labs and Pax Labs
 - J.Y. et al. v. JUUL Labs
 - Viscomi et al v. JUUL Labs and Pax Labs

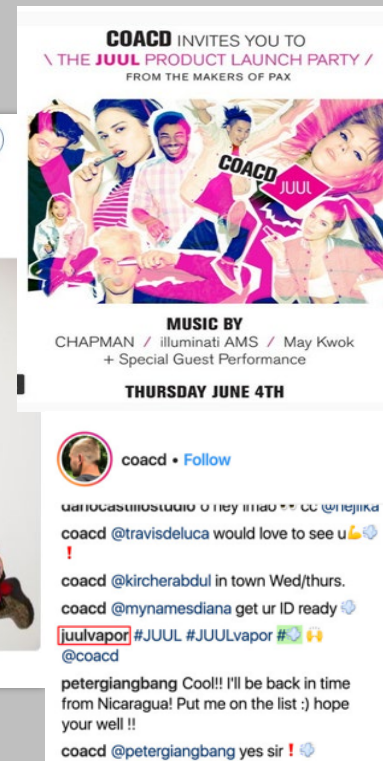
Allegations: Labeling/False Advertising

- Certain chemical in JUULs pods deliver an exceptionally potent dose of nicotine compared to traditional cigarettes
- Packaging is misleading because the dosage of nicotine stated on the packaging is lower than the actual amount of nicotine
- JUUL advertising claim that each pod is equivalent in nicotine content to a 20-cigarette pack



Allegations: Marketing Practices

- Marketing practices are creating and addicting, an entirely new group of customers who are not regular users



Questions?

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State Return-to-Play Laws and Returning to School after TBI

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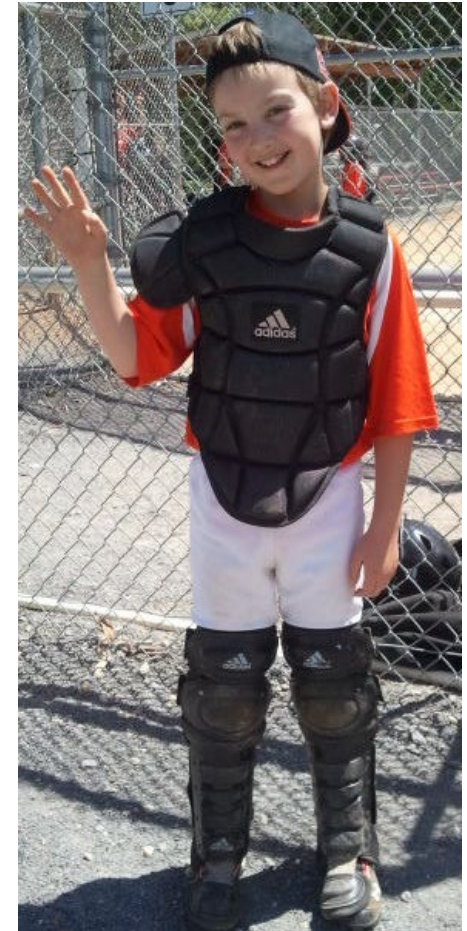


Roadmap

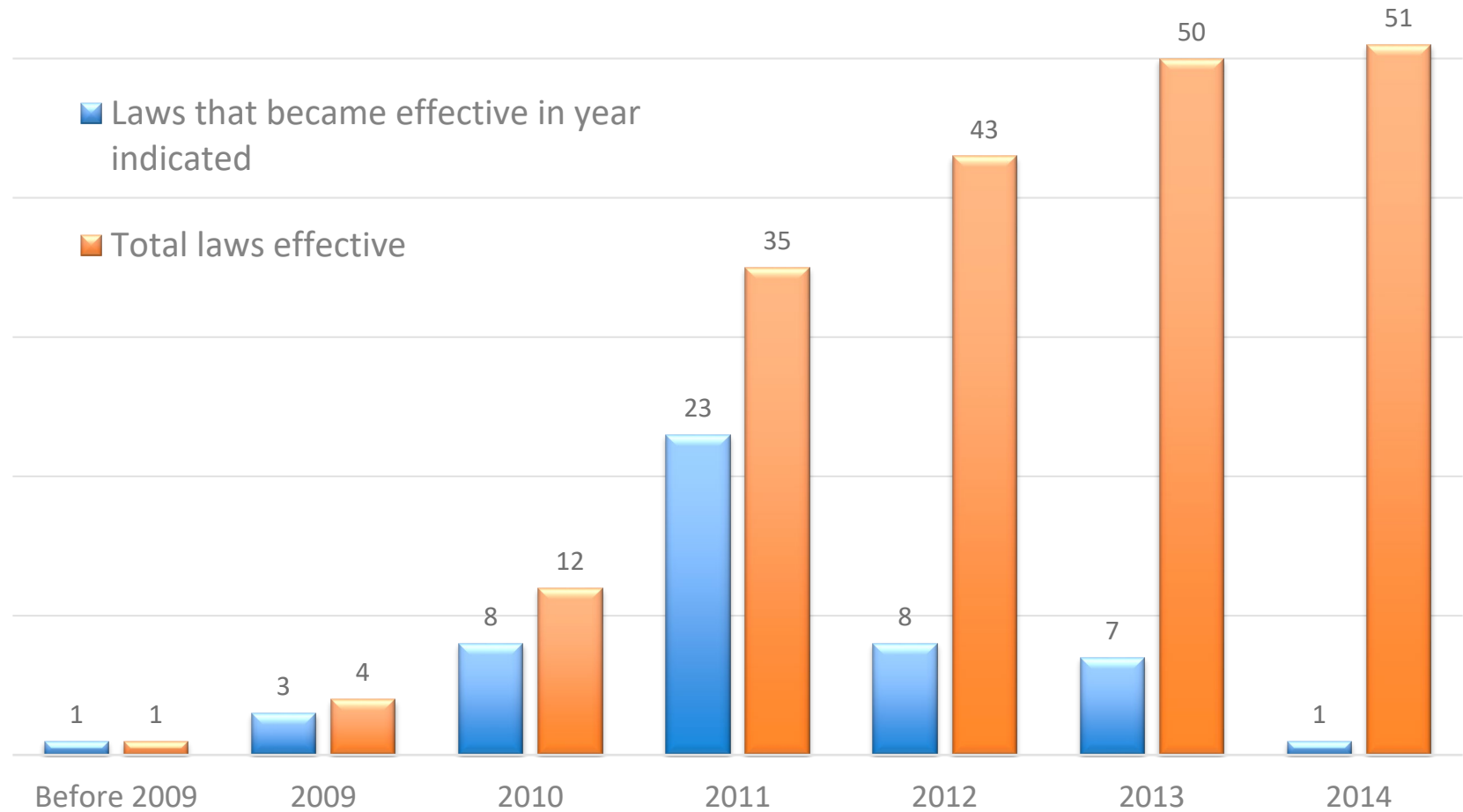
- ◆ Review state “return-to-play laws” and associated “return-to-learn” provisions
- ◆ What we learned from implementers in the field..
- ◆ Eligibility of mild TBI within federal **special education** (Section 504) and **disability** laws (Individual with Disability Act [IDEA])

Youth sports-related injury is a public health problem

- Impact on child/adolescent health is significant and worldwide
 - ✓ >7.7 million high school athletes in U.S. (NFSHSA, 2012-13)
 - ✓ ~35 million kids play organized sports each year
 - ✓ For young people aged 15-24, sports are 2nd leading cause of TBI (after MVCs)
 - ✓ Culture of youth sports in the U.S. contributing to PH burden?



State RTP Laws Enacted/Adopted by Year



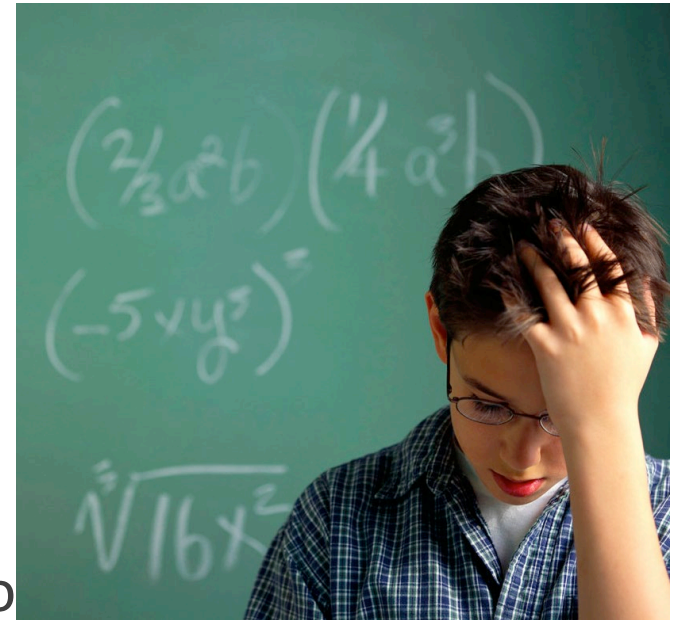
The “Big Three”: Common Provisions of RTP Laws

1. Education for student athletes and their parents (with signed information form)
2. Immediate removal of concussed athlete
3. Return-to-play restrictions with medical evaluation



Innovative Provisions of RTP Laws

- Mandatory training for coaches and officials
- Baseline testing
- Medical personnel on playing field
- Primary prevention
 - ✓ Limits on minutes of full-contact practices and scrimmages
- Training for school nurses and educators
- “Return-to-learn”



Implementation Challenges: Lessons Learned



Polar bear at Barrow High School football field (courtesy Anchorage Daily News, Sept. 2008)



“Because most of our schools in Alaska are small, remote communities with fewer than 50 students in the high school and few medical providers available, restricting the numbers who were willing to sign off made it even more difficult.”

2011 (As originally enacted):

(d) A student who has been removed from participation in a practice or game for suspicion of concussion may not return to play until the student has been evaluated and cleared for participation in writing *by a qualified person who has received training and is currently certified, as verified in writing or electronically by the qualified person, in the evaluation and management of concussions.* In this subsection, “qualified person” means either a

- (1) health care provider who is licensed in the state or exempt from licensure under state law; or
- (2) person who is acting at the direction and under the supervision of a physician who is licensed in the state...

2012 (As amended):

(d) A student who has been removed from participation in a practice or game for suspicion of concussion may not return to participation **in practice or game** play until the student has been evaluated and cleared for participation in writing by an athletic trainer or other ~~a~~ qualified person who has received training **~~and is currently certified~~**, as verified in writing or electronically by the qualified person, in the evaluation and management of concussions. In this subsection, “qualified person” means either a

- (1) health care provider who is licensed in the state or exempt from licensure under state law; or
- (2) person who is acting at the direction and under the supervision of a physician who is licensed in the state...

Evolving State Youth Sports-Related TBI Laws

- As of June 30, 2017, **35 states** had made substantive changes to their RTP laws (17 states more than once)
- Most amendments can be categorized into **3 types**:
 - ✓ Expanded coverage
 - ✓ Primary and secondary prevention
 - ✓ Tighter requirements/clarification of provisions
- As of Sept. 2018, 6 states have added RTL provisions to their RTP laws



Hawaii (*2012 Hawaii Laws Act 197*)

- Physician clearance must include return to academics

Idaho (*I.C. §33-1625*)

- Student athletes must be able to resume all normally scheduled academic activities w/o restriction or accommodation prior to RTP.

Illinois (*105 ILCS 5/22-80*)

- Concussion oversight team in each school and RTL protocol

Iowa (*IA ST § 280.13C*)

- Return to learn plans for each student in RTP protocol

Maine

- Adopt policy on management of concussive and other head injuries in school activities and athletics

Maryland (*MD Code, Education, § 7-432*)

- Appropriate accommodations

Massachusetts (*105 CMR 201.000 et seq.*)

concussion to guidelines/policies

Iowa § 280.13C (Eff. 7/2018):

*“A concussion can impair not only the physical abilities of a student athlete, but can also affect how a student athlete **thinks, acts, feels, and learns**. A student athlete who has sustained a concussion may need informal or formal adjustments, accommodations, modifications of curriculum, and monitoring by medical or educational staff until the student is fully recovered.”*

What we learned...

- ◆ Policies that focus on athletics do not cover *all* students who experience a TBI and return to school;
- ◆ Such policies often do not prioritize return-to-school over return-to-play for athletes recovering from TBI;
- ◆ The interplay between RTP legislation that includes RTS provisions and services under existing federal law (Section 504 and the Individuals with Disabilities Education Act) is not clearly understood;
- ◆ State RTP laws that contain RTS provisions can be an important tool, but can also contribute to the conflation of RTS with athletics;
Current processes that focus on athletics do not protect students from risks at school other than sports.

Applicability of Certain Federal Laws to Students with Mild TBI



Source: Loudoun Sports Injury Center

Section 504 of the Rehabilitation Act

- Civil rights law designed to protect students with disabilities from discrimination
- Requires schools to provide a “free and appropriate public education” to students with physical or mental impairments that substantially limit one or more major life activities
 - ✓ Schools must provide students with disabilities appropriate educational services to meet their needs to the same extent as the needs of students without disabilities are met (e.g., adjustments in a general education classroom or special education services)
- May apply to mTBI where recovery is prolonged
- Case-by-case determination

Section 504 of the Rehabilitation Act

- Elementary and secondary school level, law requires an individual evaluation to determine whether a student is qualified for a Section 504 plan.
 - ✓ Medical diagnosis is not an automatic qualifier. Evaluation must determine that the impairment substantially limits the student's ability to learn.
- A “**temporary impairment**” does not constitute a disability under Section 504 *unless* its severity results in a “**substantial limitation**” of at least one major life activity for an extended period of time (usually 6 months or more).
- An mTBI or concussion, which often resolves within 3-4 weeks, may be deemed a temporary impairment.

Section 504 of the Rehabilitation Act

- ADA amendments of 2008 and ADA regulations of 2016 clarify that the affected “major life activity” could include factors that impact learning, such as thinking, concentration, and/or sleeping.
- What is a “**substantial limitation**”?
 - ✓ A duration of a few weeks or even a month or two generally would not suffice. However, the Section 504 eligibility clarification seems to suggest that if the post-concussion symptoms last for period longer than a couple of months, the limitation on learning, sleep, concentration, etc. may qualify as substantial in certain cases.

Individuals with Disabilities Education Act (IDEA)

- Federal statute that grants money to states to administer special education programs
- Students recovering from TBI qualify for consideration of an individualized education plan (IEP) under the IDEA
 - ✓ Students with mTBI or concussion who have a shorter recovery time—less likely to meet eligibility requirements for services under IDEA
- “Child find” requires formal eligibility evaluation
 1. Student meets the criteria for a recognized disability qualification (TBI or OHI, other health impairment) and
 2. That disability has an adverse effect upon educational performance such that SE is warranted.
- Medical experts seem to agree that need for IEP after mTBI would be rare, no studies have confirmed this.

Another Issue: Real and Perceived Barriers to Communication among Providers, Schools, and Parents



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Food Insecurity and SNAP: Impact of the 2018 Farm Bill



Food Security



***Having access at all times to enough food for an active, healthy life
for all household members***

Health Effects of Food Insecurity

- Hypertension
- Coronary heart disease
- Hepatitis
- Stroke
- Cancer
- Diabetes
- Arthritis
- Chronic obstructive pulmonary disease
- Obesity
- Greater healthcare use and costs
 - more ED visits
 - more hospitalizations
 - longer hospital visits
- **Estimated \$160 Billion in Health Related Costs (2014)**



Food Insecure Children are at Greater Risk for . . .

- Birth defects
- Anemia
- Lower nutrient intakes
- Cognitive problems
- Aggression and anxiety
- Being hospitalized
- Poorer general health
- Having asthma
- Behavioral problems
- Cardio vascular disease
- Cancers
- Auto immune disease
- Depression
- Worse oral health.
- Toxic stress
- Obesity
- Poor academic performance
- Not graduating from high school



Food Insecurity in the United States:2017



- **Over 40 Million Americans/ 12.5% of population**
- **12.5 million children in food insecure households**
 - 1 out of 6 Children
- **Racial Disparities in Food Insecurity**
 - 8.8% of White households
 - 18.0% of Hispanic households
 - 21.8% of Black households
 - 25% of American Indian and Alaska Natives

Supplemental Nutrition Assistance Program (SNAP):

Largest Nutrition program in the country

- » FY 2017-42.1 million Americans
- » FY 2016-44.3 million Americans
- » FY 2015-45.8 million Americans
- » FY 2014-46.6 million Americans
- » FY 2013-47.6 million Americans

Largest budget item in Farm Bill

- » FY 2017-\$63.6 Billion in benefits
- » FY 2016- \$66.5 Billion in benefits
- » FY 2015-\$69.7 Billion in benefits
- » FY 2014-\$70 Billion in benefits
- » FY 2013-\$76 Billion in benefits

93% of funding goes to purchase food



2018 Farm Bill—The Story So Far

- The House and Senate both passed versions of the bill but couldn't reconcile their different approaches.
- The deadline for the 2018 Farm Bill, Sept. 30th, was missed.
- SNAP is/was the main point of contention.
- Senate wanted to leave key provisions untouched and the House wanted to make critical changes that would drastically impact food security.
 - ❑ House Bill Changes: Estimated to Save Federal Government **\$17 billion** over ten years while between **1-2 million people** would lose their SNAP benefits
- At the heart of the debate was SNAP's work requirements.



Able-bodied Adults Without Dependents (ABAWDs)



- Created by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996
- Generally: Created a work requirement for adult beneficiaries without dependents, but provided a system of exemptions and waivers to provide some flexibility in state administration.
- In proposed 2018 Farm Bill, the House wanted to increase the number of people who need to comply with work requirement and increase the amount of work required to satisfy the requirement

ABAWDs: Who it Applies to

Now

Individuals 18-49

- **Exempted if under 18 or age 50 and up**

Exempt if

- **Caring for a child under 18 years of age**
- **Caring for an incapacitated adult**
- **Deemed physically or mentally unfit for employment**
- **Pregnant**

HR 2- House Farm Bill

Individuals 18-59

- **Exempt if under 18 or age 60 and up**

Exempt if

- **Caring for a child under 6**
- **Caring for an incapacitated adult**
- **Deemed physically or mentally unfit for employment**
- **Pregnant**

ABAWD: What it Requires

Now

- **Requires covered individuals to**
 - work 20 hours or more per week, averaged monthly;
 - participate in and comply with the requirements of a work program for 20 hours or more per week
 - Or a combination of work/training programs at least an average 20 hours/week each month
- **If fail to comply then limited to 3 months of Benefit in a 36 month period**
- **ABAWDs need to report when their circumstances change (no longer meeting requirements)**
- **Most states collect detailed income and work data every 6 months**

HR 2: House Farm Bill

- **Raise work requirement to 25 hours/week starting in 2026**
- **ABAWDS would need to prove every month that they met the work requirement of 25 hours/ week**

ABAWD: Geographic Waivers

Now

- States can request a waiver from USDA (Food and Nutrition Services) for areas with scarcity of economic opportunity
- Waiver typically 1 year (but can be less or up to 2 years)
- State needs to prove low-employment opportunities
 1. **Unemployment rate over 10%**
 2. **Area has been designated a Labor Surplus Area by Department of Labor or**
 3. **24 Month average unemployment rate is 20 percent above the National Average for the same time period**

HR 2: House Farm Bill

Reduce states' ability to grant geographic waivers by

- **Creating a floor for the 24 month average waiver process. Must be 20% above the national average and at least 6% unemployment rate.**
- **Before if the national average was 4% unemployment you could seek a geographic waiver if your unemployment was 4.8% or higher. But states would not be able to under this proposal because had not reached the floor of 6%.**

ABAWD: Individual Waivers (15% Exemptions)

Now

- Each month states can grant individual exemptions from the work requirement (ABAWD) to 15% of their SNAP caseload

HR 2: House Farm Bill

- States would only be able to grant individual exemptions from the work requirement (ABAWD) to **12% of their caseload**
 - » **20% decrease in the available individual exemptions.**

Where We Are Now

- **2018 midterm elections occur in November and change the political make-up of the house**
- **House and Senate restart negotiations regarding the Farm Bill**
- **End of Nov. House and Senate announce that they have reached an agreement on the 2018 Farm Bill and indicate new work requirements will not be part of the Bill.**
- **Finalize deal to be revealed and this week.**
- **But. . . .**



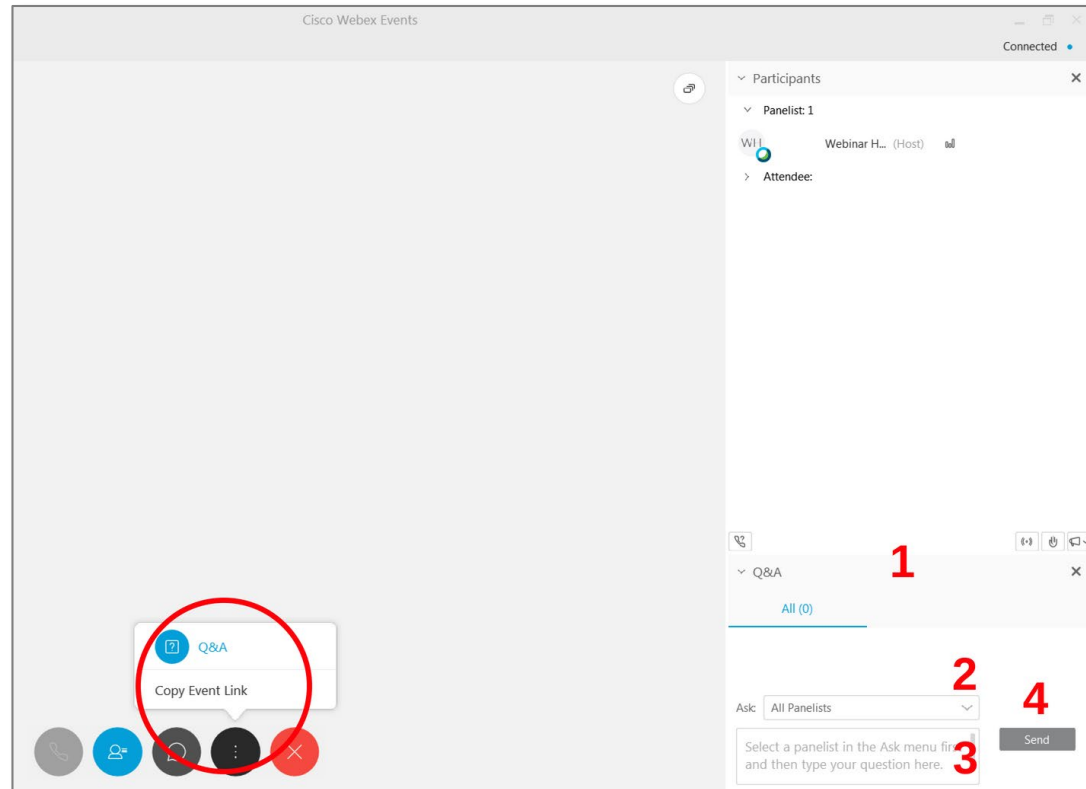
Potential Proposed Regulations

- **Secretary of Agriculture Sonny Perdue announced that USDA will be issuing proposed rule to crack down on work-requirement waivers.**



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