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**2020 – A LOOK AHEAD AT THE POLICY
ISSUES IMPACTING CME**

JANUARY 10, 2020

-SAN FRANCISCO, CA-

Speakers

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- ❖ Founding Partner, Thorn Run Partners (TRP)
- ❖ 25 years of experience as a lobbyist, Capitol Hill staffer and health policy expert
- ❖ Served on the committee (Senate Health, Education, Labor and Pensions) and personal staffs of Senator Edward M. Kennedy (D–MA)

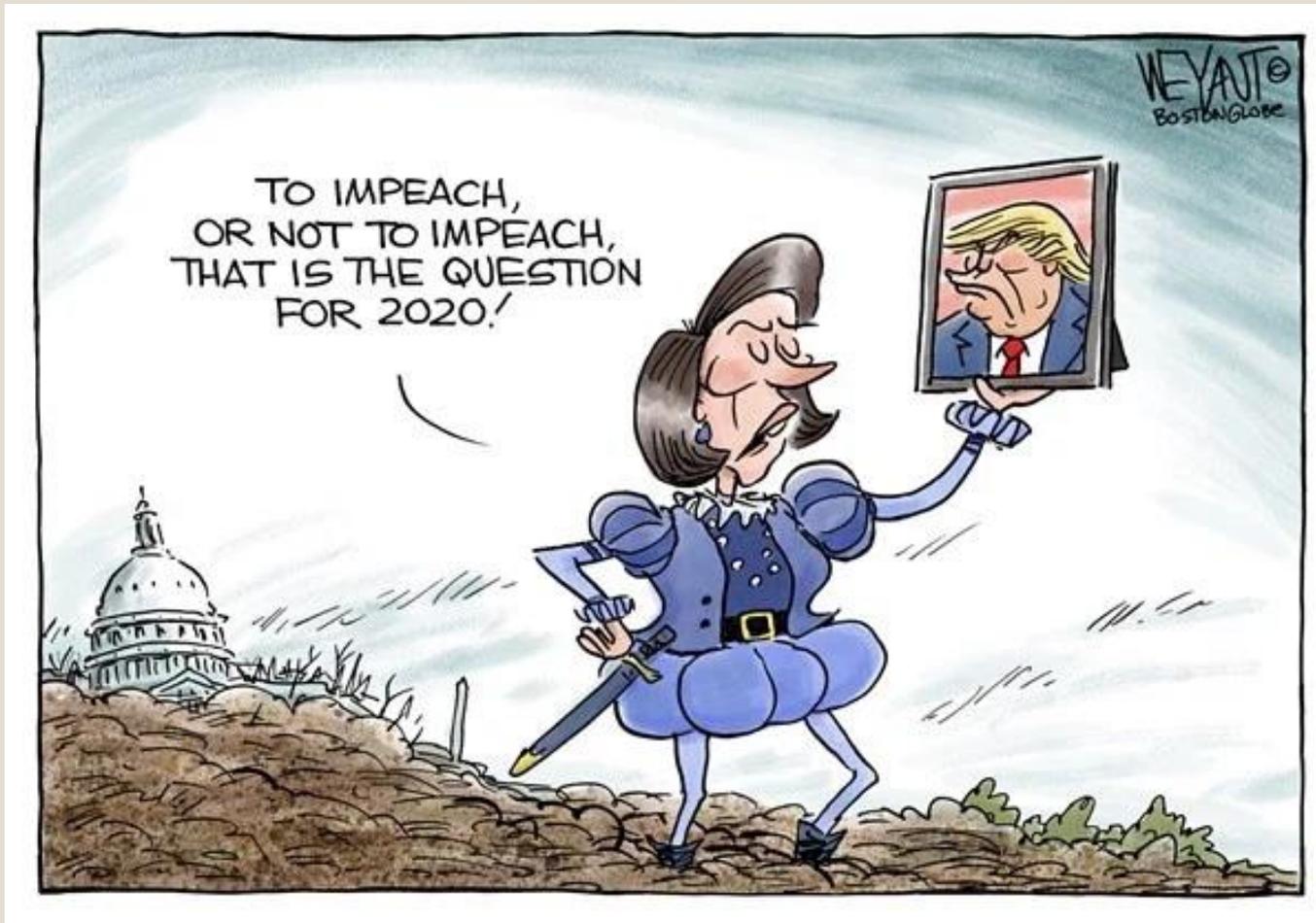
Tom Sullivan



- ❖ Founding Member, CME Coalition
- ❖ President/CEO, Rockpointe
- ❖ Editor/Publisher, Policy and Medicine
- ❖ Former Political Consultant

DC... A Live Shot from the Capitol

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Let's Level Set

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Everything 2020 through the lens of politics...

❖ *White House*

- ❖ Re-election is everything
- ❖ Expect more base politics, embrace of impeachment

❖ *Senate*

- ❖ Republicans pin hopes on maintaining majority (current: 53-47)
- ❖ Focus on key races: AZ, ME, CO, IA, AL (D), MI (D)
- ❖ McConnell unlikely to take up major legislation

❖ *House*

- ❖ Pelosi looking to protect her majority in swing, suburban districts
- ❖ With impeachment behind them (?), Democrats will look for ways to hold onto their lead – the challenge is to satisfy the liberal base without creating problems for the moderates

The New Policy Dynamic: How things get done

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1. **Big EOY packages at major funding deadlines**
 1. 2019 saw ACA taxes repealed, federal government funding, and Tobacco 21 all passed as part of a huge package
 2. Several health programs have received short-term extensions, setting up a new May 2020 deadline
2. **White House-driven initiatives via rulemaking**
 1. Drug Importation
 2. International Reference Pricing (for drugs)
3. **Lame duck sessions after Presidential elections**
 1. 21st Century Cures / Cures 2.0?

Big Picture: Lawmaking has Changed

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- By and large, so-called regular order and Senate floor votes are no longer the way big things get done.
- Instead things get done when the 4 corners (leadership) plus the White House cut massive deals at the deadline, and then force their respective caucuses to take a big swallow.

But it's important to recognize that these big deals don't just materialize out of ether; their underlying merit has been lobbied for months or longer to get them in a position to pass.

Deciphering Trump

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Donald J. Trump
@realDonaldTrump

Announcing great, expanded HRAs—big win for small employers and workers. This is a fantastic plan! My Administration has worked very hard on creating more affordable health coverage.



Perspectives: Trump's new rule will give businesses and workers better health care... Employers will be able to offer their workers HRAs to buy individual market coverage for themselves and their families, writes Brian Blase, a special assistant t...
cnn.com

3:14 PM · Jun 14, 2019 · Twitter for iPhone

12K Retweets 47K Likes



Donald J. Trump
@realDonaldTrump

Will be meeting with representatives of the Vaping industry, together with medical professionals and individual state representatives, to come up with an acceptable solution to the Vaping and E-cigarette dilemma. Children's health & safety, together with jobs, will be a focus!

9:00 AM · Nov 11, 2019 · Twitter for iPhone

13.2K Retweets 61.7K Likes



Donald J. Trump
@realDonaldTrump

Everybody agrees that ObamaCare doesn't work. Premiums & deductibles are far too high - Really bad HealthCare! Even the Dems want to replace it, but with Medicare for all, which would cause 180 million Americans to lose their beloved private health insurance. The Republicans....

10:13 PM · Apr 1, 2019 · Twitter for iPhone

15.3K Retweets 69.9K Likes



Donald J. Trump
@realDonaldTrump

...are developing a really great HealthCare Plan with far lower premiums (cost) & deductibles than ObamaCare. In other words it will be far less expensive & much more usable than ObamaCare. Vote will be taken right after the Election when Republicans hold the Senate & win.....

10:23 PM · Apr 1, 2019 · Twitter for iPhone

14.5K Retweets 67K Likes



Donald J. Trump
@realDonaldTrump

America's great USMCA Trade Bill is looking good. It will be the best and most important trade deal ever made by the USA. Good for everybody - Farmers, Manufacturers, Energy, Unions - tremendous support. Importantly, we will finally end our Country's worst Trade Deal, NAFTA!

9:32 AM · Dec 10, 2019 · Twitter for iPhone

20.8K Retweets 85.8K Likes



Donald J. Trump
@realDonaldTrump

Lowering drug prices for many Americans - including our great seniors! At my direction, @HHSGov @SecAzar just released a Safe Importation Action Plan. Our Governors will be very happy too! @GovRonDeSantis @GovofCO



Secretary Alex Azar
@SecAzar · Jul 31, 2019

Today we are announcing a new action plan to lay the foundation for the safe importation of certain prescription drugs. This is the next important step the Administration is taking to address foreign freeloading and lower the cost of drugs for Americans: hhs.gov/about/news/2019-07-31

11:10 AM · Jul 31, 2019 · Twitter for iPhone

12.1K Retweets 47K Likes



Donald J. Trump
@realDonaldTrump

Because of my Administration, drug prices are down for the first time in almost 50 years — but the American people need Congress to help. I like Sen. Grassley's drug pricing bill very much, and it's great to see Speaker Pelosi's bill today. Let's get it done in a bipartisan way!

5:42 PM · Sep 19, 2019 · Twitter for iPhone

19.5K Retweets 91.1K Likes

May 22 – The Last Train out of the Station

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- As part of the 2019 EOY package, Congress punted... until May 22.
 - ✦ Pelosi hopes to use this last bite of the apple to drive concessions from drug companies on pricing...
- But do Ds really want a win on Trump's watch?
 - Will they really give him his Rose Garden ceremony during the heat of an election?
 - Also, McConnell wants to protect his Senators from a bad vote...
- We predict something modest on drug pricing – but instead look to WH action via exec order.
 - But will Trump go for tough (like the rhetoric) or soft (like vaping)?

This won't make it any easier: Internal Strife at HHS

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- Azar and Verma are at war – to the point that the pair were summoned for a meeting with VP Pence in December.



HHS Secretary Azar

- Tried to prevent Verma from traveling with President Trump on Air Force I.
- Has clashed with the White House DPC on major policy proposals, such as drug pricing, where Verma sided with Grogan.
- Spiked an ACA alternative plan that Verma spent months crafting.

CMS Administrator Verma

- Spent over \$3M on communications contracts at CMS to raise her profile.
- Claims she's been discriminated against because of gender.
- Has been accused of creating a hostile working environment within CMS.
- Sought taxpayer reimbursement for stolen jewelry.

CME Coalition: 2019 in Review

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- Despite the disfunction in Washington, the CME Coalition had a very successful 2019:
 - CME for MIPS
 - Open Payments Simplifications
 - An Explosion of Capitol Hill Activity
 - State Laws

CME for MIPS (1/2)

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- The CME Coalition has championed CMS for recognizing Quality Improvement continuing medical education (QI-CME) as an 'Improvement Activity' under Medicare's new Merit-Based Incentive Payment System (MIPS).
- In coordination with the ACCME, the CME Coalition has developed a logo and official descriptive language identifying accredited CME activities that meet CMS' standards under MIPS.
- The CME Coalition encourages CME provider organizations to utilize this logo and language to signify all activities that meet the CMS MIPS requirements.



“Completion of this accredited CME activity meets the expectations of an Accredited Safety or Quality Improvement Program (IA_PSPA_28) for the Merit-based Incentive Payment Program (MIPS).”

CME for MIPS (2/2)

- In the FY 2020 Medicare Physician Fee Schedule, CMS adopted a recommendation from the Coalition to align FDA’s REMS program with QI-CME under MIPS.
- For the first time, the agency cites CME related to opioid analgesic REMS as a primary example of the type of activity that meets the requirements for physicians to satisfy this Improvement Activity.

Proposed Change and Rationale:

Addition of “An example of an activity that could satisfy this improvement activity is completion of an accredited continuing medical education program related to opioid analgesic risk and evaluation strategy (REMS) to address pain control (that is, acute and chronic pain)” as an example of an accredited continuing medical education (CME) program that could meet this improvement activity. Due to the importance of safe prescribing to prevent opioid misuse and opioid use disorder, CME programs related to opioid analgesic REMS may be especially useful to MIPS eligible clinicians in their attempts to prevent opioid misuse among their patients and combat the opioid epidemic.

MIPS Value Pathways (MVP's)

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- MVPs are predetermined subsets of measures and activities
 - Relevant to a clinician's scope of practice and
 - Integrated across the different MIPS categories.
- Instead of choosing measures and activities to report for each category, MIPS participants would report one MVP, including all measures and activities in the MVP.
- The shift to MVPs is a shift from flexibility to standardization. CMS stated, "While we emphasized *flexibility* during the initial years of MIPS, we believe we must balance flexibility with a degree of *standardization*..."

CMS Video

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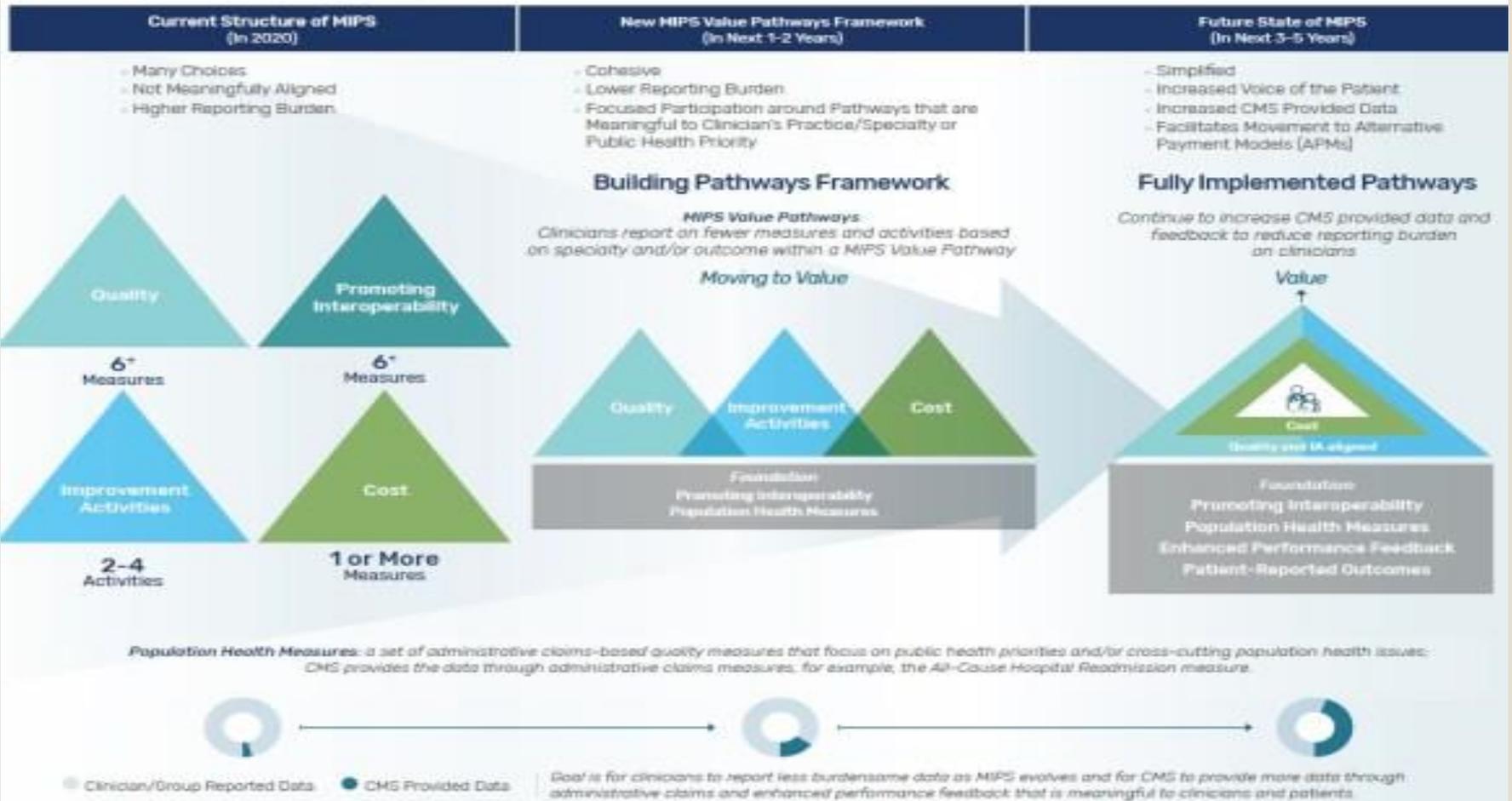
CMS Guiding Principles of MVP's

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- “MVPs should consist of limited sets of measures and activities that are meaningful to clinicians, which will reduce or eliminate clinician burden related to selection of measures and activities, simplify scoring, and lead to sufficient comparative data.”
- “MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care.”
- “MVPs should include measures that encourage performance improvements in high priority areas.”
- “MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.”

MIPS VALUE PATHWAYS (MVP example)

MIPS Value Pathways



CME and MIPS Value Pathway

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- MVP begins in 2021
 - CMS Seeking Comments and suggestions
- CME Coalition Commented on including CME in the volume pathway
- Working with a coalition of organizations to educate on the value of CME and ensure CME is included in the MIPS value pathways

The Latest on Open Payments

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- In another development from the FY 2020 Physician Fee Schedule, CMS is adopting some minor simplifications for Open Payments reporting as it pertains to CME.
- CMS is consolidating two separate categories for CME programs: while previous regulations had distinguished between accredited/certified and unaccredited/non-certified continuing education programs, the new proposal would consolidate these categories.
 - In effect, this would eliminate the ambiguity caused by having a separate category for accredited CME (which is exempted) and is likely a recognition that the existence of this category was superfluous given their guidance on reporting for these events.
- **Key takeaway:** Nothing in this proposal would impact existing guidance (FAQ #8165) that exempts accredited CME from reporting in the Open Payments database.

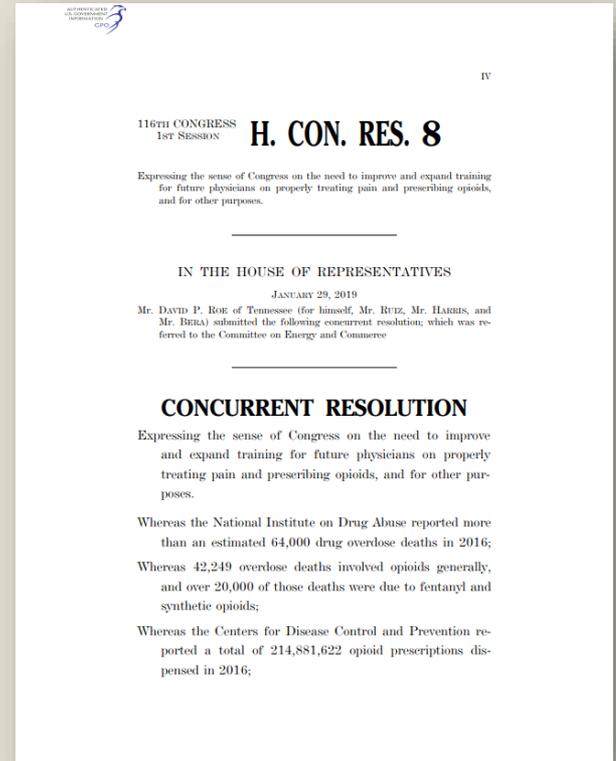
CME on Capitol Hill: Drug Pricing

- **Proposals to encourage CME on biosimilars:**
 - An agreement released by the House Energy & Commerce Committee and Senate HELP Committee includes a provision requiring the Secretary of HHS to “develop and improve continuing education for health care providers regarding biological products.”
 - House and Senate Republicans released an alternative to Speaker Nancy Pelosi’s (D-CA) prescription drug pricing plan that includes a provision that “provides for increased education on biosimilars by providing certain educational materials and continuing education to physicians, crediting to MIPS.”
- The CME Coalition helped consult during the drafting of the legislation and has been active on Capitol Hill to ensure the provision is included in any package of drug pricing legislation passed (potentially in May 2020).

CME on Capitol Hill: House Resolution

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- Reps. Phil Roe (R-TN), Raul Ruiz (D-CA), Andy Harris (R-MD), and Ami Bera (D-CA) recently introduced a congressional resolution expressing support for the need to expand training for physicians on opioid prescribing.
- Congress may revisit opioid legislation in 2019 or 2020, and lawmakers continue to see a role for prescriber education.



CME on Capitol Hill: Other Key Bills

Bill #	Official Title	Lead Sponsor(s)	Summary
S.1129 H.R.1384	Medicare for All Act	Sen. Bernie Sanders (I-VT) Rep. Pramila Jayapal (D-WA)	Among other things, establish national minimum standards for institutional providers of services and individual health care practitioners, including requirements related to the number of or type of required continuing education hours.
S. 402 H.R.1082	“Survivors’ Access to Supportive Care Act”	Sen. Patty Murray (D-WA) Rep. Pramila Jayapal (D-WA)	Provides grants to states to identify the availability of continuing education for sexual assault forensic examiners.
H.R. 647	Palliative Care and Hospice Education and Training Act	Rep. Eliot Engel (D-NY)	Supports continuing education of health professionals who provide palliative care to patients with serious or life-threatening illness
S.299	Geriatrics Workforce Improvement Act	Sen. Susan Collins (R-ME)	Provides grants for the establishment or operation of Geriatrics Workforce Enhancement Programs, which are required to report on, among other things, the number of faculty and practicing professionals who participated in continuing education programs.
H.R.826	End Neglected Tropical Diseases Act	Rep. Chris Smith (R-NJ)	Provides grant funds which may be used for clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to neglected tropical diseases.
S. 498	Assessment of the Indian Health Service Act of 2019	Sen. Mike Rounds (R-SD)	Requires the GAO and OIG to study for the Indian Health Service, how much time is spent on training and participating in continuing education courses for the approximately 3,700 Medicaid-reimbursable full-time equivalent employees.

'Gift Bans' in the States

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New Jersey

- In May, the New Jersey Attorney General finalized amendments to the rules governing physician interactions with pharmaceutical companies.
- The final rules reflect feedback from stakeholders on the scope of the rules, meal limits, the \$10,000 bona fide services cap, and changes to definitions such as “education event,” “prescriber,” and “research.”

Maine

- The Maine Board of Pharmacy released a Notice of Agency Rule-making Proposal to update definitions in the state's gift ban law enacted in 2017.
- The law would essentially ban manufacturers or wholesalers, including its agents, from offering or giving a practitioner a cash gift in any amount ... for which reciprocity is expected or implied.

CME Coalition Plan for 2020

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- **Congressional Briefing**

- The CME Coalition will execute a Congressional Briefing highlighting the benefits of CME in 2020 that will serve as a mechanism for identifying and securing congressional champions for our agenda.

- **Best Practices Guidance**

- The Coalition will develop a written manual and instructional video, in cooperation with our legal counsel, on best practices for CME supporters and practitioners.

- **ACCME Standards for Commercial Support**

- The Coalition will support the ACCME Standards for Commercial Support review process through the collection and submission of comments, engagement, and guidance

- **MIPS-creditable CME Info Hub**

- The Coalition will support the creation of an online repository for a compendium of MIPS-creditable CME activities

- **State Activity**

- The Coalition will continue to actively monitor and fight state legislative attempts to curb CME activities/events

- **Stakeholder Engagement / Thought Leadership**

- We will continue to represent the CME “enterprise” and to educate the broader stakeholder community at national conferences and through webinars

Discussion

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Other issues we should know about?

Thank you!

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