MID-YEAR LEGISLATIVE, REGULATORY & LEGAL ROUND-UP

Written By Chris Condeluci

With the U.S. Congress and state legislatures adjourned for the summer and important legal cases still pending, this is a good opportunity to provide a quick round-up of the latest developments and related SIIA engagement.

The Prospects of Legislation Regulating Artificial Intelligence (AI) Dim: SIIA has reported in our Government Relations Newsletters and Webinars that a bi-partisan group of Senators – led by Senate Majority Leader Chuck Schumer (D-NY) – are "all in"

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on enacting some form of AI regulation. Specifically, this bi-partisan group released a report titled Driving U.S. Innovation in Artificial Intelligence in which these Senators called for legislation that would:

- Increase Funding for AI Innovation
- Develop Nationwide Standards for AI Safety and Fairness
- Strengthen National Security
- Address Potential Job Displacement Due to AI
- Tackle "Deepfakes" and Election Interference

When it comes to healthcare and AI, these Senators called for the continued deployment of AI in healthcare, but they stressed the need to implement appropriate guardrails and safety measures. This bi-partisan group also wants Congress to consider policies to promote innovation of AI systems that meaningfully improve health outcomes and efficiencies in healthcare delivery, but they want to make sure that patients are informed when a medical recommendation or prescription is AI-generated or furnished by an actual medical provider.

Upon the release of the Report, Senate Majority Leader Schumer publicly stated that he wants Congress to pass AI-related legislation by the end of 2024, which begs the question: If AI legislation is bi-partisan (and it's backed by Senate Democratic Leadership), will the Senate – followed by the House – pass some form of AI-related legislation this Congress? Our answer: While never a guarantee, AI-related legislation could be taken up and passed during the "Lame Duck" session after the November elections.

HOWEVER, recent comments from House Republican Majority Leader Steve Scalise (R-LA) have thrown cold water on the prospects of passing legislation regulating AI by the year's end. Majority Leader Scalise recently explained that House Republicans do not support legislation that would create new government agencies, new licensing requirements, and funding and research that might favor one technology over another. Leader Scalise further explained that, ultimately, House Republicans want to make sure that "government" does not get in the way of the innovation that is already underway.

While the prospects of something happening in Lame Duck looked promising due in large part to Senate Majority Leader Schumer's endorsement of getting something done by the end of 2024, those prospects have dimmed due to House Majority Leader Scalise's comments. SIIA will continue to track the ups and downs of Congress's efforts to regulate AI.

Unworkable Proposed Mental Health Parity Regulations Could Be Final Soon: Back in July 2023, the Biden Administration released proposed regulations intended to increase access to mental health and substance use disorder (MH/SUD) benefits through increased compliance with the Mental Health Parity requirements. These proposed regulations focused exclusively on Non-Quantitative Treatment Limitations (NQTLs) (such as prior authorization, concurrent review, and other utilization management tools) that self-insured plans impose on MH/SUD benefits, requiring plans to ensure that the NQTLs imposed on MH/SUD benefits are comparable to the NQTLs imposed on medical and surgical (M/S) benefits. According to the proposed regulations, to remain compliant with the Mental Health Parity law, plans would be required to comply with a number of mathematical tests – and satisfy various definitions – used to determine whether an appropriate level of comparability is present.

The employer community – including SIIA – has told the Biden Administration in multiple comment letters submitted back in October 2023 that the above-stated proposed requirements are unworkable and that the proposed tests and definitions amount to benefit mandates. We also explained that the proposed tests are impossible for self-insured plans to operationalize and that these new requirements could force employer and union plan sponsors to remove nearly all utilization management tools that they currently use to ensure that employees and their dependents receive safe and appropriate care. We further stated that, in the end, the proposed regulations could lead to the unintended consequence of decreasing access to MH/SUD benefits.

What's the alternative? The employer community – including SIIA – has been busy telling the White House and Congressional staff that a better approach to increasing access to MH/SUD benefits includes:

- Prioritizing training and treatment integration for primary care physicians and the front-line healthcare workforce to better identify and treat mental health and substance use disorders before they worsen.
- Increasing access to telehealth to enable mental health professionals to treat patients no matter where they live. Telehealth enables employees and their families to obtain the care they need, when and where they need it, in an affordable and convenient manner.
- Establishing long-term programs to build out the mental health workforce, such as programs to incentivize more medical students to enter the mental health field and to increase the supply of qualified clinicians.

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Despite our efforts to suggest workable alternatives to achieving the Biden Administration's policy goal of increasing access to MH/SUD benefits, the Administration is inching toward finalizing these unworkable proposed requirements. We could see final regulations sometime this summer. SIIA will continue to monitor the Administration's activities in this important area.

Fiduciary Issues Impacting Self-Insured Health Plans Take Center Stage, And SIIA Responds: With the advent of the employee-participant lawsuit against Johnson & Johnson claiming breach of their fiduciary duties for failing to prevent the self-insured health plan from overpaying for covered benefits – followed by another employee-participant lawsuit against the Mayo Clinic lawsuit alleging fiduciary breach for underpaying out-of-network providers which produced balance bills for the participant – plan sponsors and the need to adhere to their fiduciary duties are under a microscope.

Add in a lawsuit filed by the Department of Labor (DOL) against Blue Cross/Blue Shield of Minnesota (BCBS of MN) in which the DOL alleges that BCBS of MN wrongfully used "plan assets" to pay a provider tax imposed on providers in BCBS MN's network; plan sponsors have been put on notice that failure to examine and analyze health claims data and the failure to discover things like hidden fees and/or overpayments could expose the plan sponsor to fiduciary liability (actionable by plan participants, but also the DOL).

SIIA's Price Transparency Committee has developed various fiduciary "must-dos" that (once released) SIIA members may share with their clients and internally with their workforce. These fiduciary "must-dos" speak to four key concepts that every plan sponsor must know. They include:

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- Prudent Decision-Making: A plan sponsor – as a fiduciary – must make ALL plan-related decisions "prudently." Here, the plan sponsor's decision-making must always take into account the best interests of employees and their family members participating in the plan. Such decisions must be made in a way that illustrates that the plan sponsor took the appropriate amount of time and due care to think about the outcomes of the decision.

- Process: Prudent decision-making can be illustrated through the development of a "process" that (1) justifies the decision-making and (2) creates a record that tangibly shows that the plan sponsor spent the time and effort to think through matters like:

    - What benefits and services should the plan cover and not cover?
    - The cost of covered benefits and whether those costs are reasonable.
    - The fees paid to your broker, benefit consultant, and the plan's service providers.

  Importantly, the plan sponsor is NOT required to find the cheapest options for the plan and its participants. Rather, the plan sponsor must choose the best options that the plan sponsor reasonably believes provide the best value to the plan and its participants.

- Review: Upon the establishment of a self-insured health plan, the plan sponsors will enter into agreements with brokers, benefit consultants, and specified entities providing services to your plan such as (1) a Pharmacy Benefit Manager (PBM), (2) the owner of the medical and/or prescription drug networks that plan participants may access, and (3) a third party that will adjudicate, process, and pay health claims incurred by plan participants, and also, provide management services to the plan and its participants.

    - In these cases, the plan sponsor – with the assistance of in-house counsel or an outside ERISA attorney – must review these agreements for accuracy, for indemnification of liability, and for purposes of determining whether the fees charged by these entities are reasonable. In addition, this review must ensure that (1) the plan sponsor has access to a complete and accurate set of health claims data, (2) there are no unreasonable limitations placed on plan sponsor's ability to audit these entities to determine if, for example, claims are being properly paid, and (3) the plan's service providers are keeping confidential any participant-related information and they remain subject to liability for any confidentiality breach of any kind.

- Monitoring: Plan sponsors must continually monitor ALL of the entities providing services to the plan. This includes the plan's broker, benefit consultant, PBM, owners of the provider networks, and the claims adjudication and management services TPA. Such monitoring requires ongoing determinations that (1) the fees charged to the plan are reasonable, (2) health claims are being properly paid, and (3)

each entity is adequately performing the services they were hired to perform. This also includes receipt of a required compensation disclosure from brokers, benefit consultants, PBMs, and TPAs providing specified services to the plan (known as a "408(b)(2)(B) compensation disclosure")

- Plan sponsors should also remain informed about (1) the fees charged and (2) the types of services performed by other plan service providers that the sponsor may consider contracting with, especially in cases where, upon monitoring existing service providers, the sponsor determines that these existing service providers are not adequately performing the services they were hired to perform.

The complete fiduciary guidance can be accessed through the Resources section of the SIIA website at www.siia.org. ■

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