AMA AMERICAN MEDICAL ASSOCIATION

Advocacy Resource Center

Advocating on behalf of physicians and patients at the state level

Midyear review: August 2019

This year, states faced a flurry of legislation concerning the ever-present discussions surrounding the nation's opioid epidemic; physician-insurer relations; scope of practice; public health issues; and more. Out-of-network coverage was again a prominent issue, as were Medicaid work requirements. Additionally, ongoing debates over insurer efforts to control utilization affected many states, including how these insurer barriers may be standing in the way of patients with opioid use disorder accessing care. Finally, the CVS-Aetna deal challenged stakeholders to understand the impact of this unique and massive merger on health care competition, and remains unsettled at the time of writing.

During these legislative, regulatory and private sector issues, medical societies continued to show their value and won more often than can be counted in a single document. In part, this was due to working with state legislatures on solutions, developing coalitions and seeking the best resources from around the country. The American Medical Association (AMA) Advocacy Resource Center has been pleased to contribute to the success of many state and national medical specialty society efforts, and we welcome the opportunity to share our expertise, reach out to our colleagues and enlist the AMA on your behalf. This report provides an overview of many 2019 developments to date.

Please refer to the Advocacy Resource Center website for resources relating to our state advocacy campaigns and for a list of Advocacy Resource Center attorneys and areas of expertise.

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CVS-Aetna Merger

Overview

CVS-Aetna announced their proposed merger on December 3, 2017. The CVS-Aetna merger is a horizontal and a vertical merger. In horizontal mergers, two competitors combine, and CVS-Aetna are significant competitors in numerous Medicare Part D geographic markets. They also compete in pharmacy benefit management (PBM) services. In many additional markets, the merger is "vertical" because Aetna is a buyer of inputs (such as PBM services and pharmacy) that CVS sells. The AMA has never opposed a vertical merger—it has only challenged horizontal mergers of health insurers, with varying degrees of success. Vertical mergers' impacts are much more difficult to determine than horizontal mergers.' Compared with horizontal mergers, very little economic research and legal guidance about vertical mergers exists. These factors make it difficult to determine whether opposition to a vertical merger can succeed. Nevertheless, once our evidence was amassed and our experts had completed their thorough and rigorous analysis, AMA determined that there was only one position to take vis-à-vis this proposed merger: that it must be blocked.

2018-2019 Significant activity

The AMA has taken a leading role in challenging the massive CVS-Aetna merger, the largest in the history of U.S. health care. If approved, the merger would hurt competition in five key health care markets: Medicare Part D prescription drug plan (PDP); health insurance; pharmacy benefit management; retail pharmacy; and specialty pharmacy. The AMA opposition is evidence-based, the result of months of analysis by nationally-recognized health economists and legal experts. The AMA's advocacy led to an almost unheard-of development: a federal judge holding hearings to evaluate the settlement between the U.S. Department of Justice (DOJ) and CVS-Aetna that got the DOJ to approve the merger. The settlement specifically called on Aetna to divest its Medicare Part D stand-alone prescription drug plan (PDP) business. Key activities include:

- July 2019: On July 19, the AMA made closing arguments before Judge Richard Leon (Judge Leon), the federal district court judge responsible for approving the consent decree between the DOJ and CVS-Aetna. The AMA urged Judge Leon to block the merger.

- June 2019: During evidentiary hearings from June 4-6, witnesses from CVS-Aetna and from friends of the court, or "amici," testified about the merger. The AMA was one of three amici asked to testify. Dr. Neeraj Sood, PhD, Professor & Vice Dean for Research at the University of Southern California Sol Price School of Public Policy and Director of Research at the Leonard D. Schaeffer Center for Health Policy & Economics, testified on behalf of the AMA.

- May 2019: On May 13, Judge Leon decided that he wanted to hear from six witnesses about the merger: three for the amici or "friends of the court" and three for DOJ/CVS-Aetna.

- April 2019: The AMA participated in the April 5 status hearing before Judge Leon, arguing the points made in its brief and in favor of having a subsequent hearing where witnesses may present evidence.

- March 2019: AMA filed a brief with Judge Leon, explaining why the DOJ's settlement with Aetna does not adequately address with the merger's anticompetitive effects. The AMA made three main points:

  - The divestiture would decrease the number of firms in already concentrated and rapidly consolidating PDP markets;
  - New entry will not solve the problem because there are high barriers to entry into PDP markets; and
  - The merger and divestiture would eliminate the unique and important role of competition between Aetna and CVS in the PDP market.

- Judge Leon decided to set a status hearing on April 5 to discuss next steps in the merger review, e.g., whether witnesses should testify about the merger. Judge Leon's decision was a highly unusual development because with a hearing pursuant to the Tunney Act, hearing from live witnesses is almost unheard of.

- February 2019-November 2018: The AMA submitted its Tunney Act comments regarding the CVS-Aetna merger to Judge Leon. Judge Leon held several hearings, at which he expressed concerning regarding how the DOJ handled the merger. During the hearings, Judge Leon also signaled that that he was aware of the AMA's advocacy as it related to this merger and specifically, that he expected (and was waiting for) AMA to file Tunney Act comments.

- October 2018: The DOJ announced that it had approved the merger via consent decree, on the condition that Aetna divest its PDP business. That same day, the AMA issued a press release, stating that it was disappointed that the DOJ did not block the entire merger.

- August 2018: The AMA submitted a comprehensive analysis of the CVS-Aetna merger to the DOJ stating that the CVS-Aetna merger was anticompetitive because it was likely to substantially lessen competition in PBM services, health insurance, retail pharmacy, PDP and specialty pharmacy, and asked that the DOJ oppose the merger. The AMA's opposition was based on reports (which were attached to the AMA statement) by the following nationally recognized experts:

  - Lawton "Rob" Burns, PhD, Professor of Management and chairperson of the Health Care Management Department of The Wharton School of The University of Pennsylvania. Dr. Burns' report showed that the benefits of the proposed CVS-Aetna merger were speculative, the benefits of vertical integration were limited and retail clinics had significant shortcomings.
  - Richard Scheffler, PhD, Distinguished Professor of Health Economics and Public Policy, joint tenured appointments in School of Public Health and Goldman School of Public Policy, University of California, Berkeley. Dr. Scheffler's report described the potential anticompetitive effects that the CVS-Aetna merger would have in the PDP market across the country.
  - Neeraj Sood, PhD, Professor & vice dean for Research at the USC Sol Price School of Public Policy and Director of Research at the Leonard D. Schaeffer Center for Health Policy & Economics. Dr. Sood's report discussed the CVS-Aetna merger's potential anticompetitive effects in the insurance, pharmacy and PBM markets.
  - Amanda Starc, PhD, Associate Professor of Strategy at the Kellogg School of Management and a Faculty Research Fellow at the National Bureau of Economic Research. Dr. Starc's report showed that the CVS-Aetna merger would raise health insurance premiums, and that any cost efficiencies resulting from the merger are not likely to be passed on to consumers.

- The AMA's statement was shared extensively with state and federal regulators and legislators. AMA also reconvened its state-based workgroup to develop next steps in its advocacy strategy. The AMA and the Utah Medical Association filed a statement requesting that the Utah Commissioner of

Insurance oppose the proposed CVS-Aetna merger. On August 1, California Insurance Commissioner David Jones submitted an extensive analysis to the DOJ, recommending that the DOJ sue to block the CVS-Aetna merger. Commissioner Jones' decision was the result of extensive testimony that the AMA presented during a June 2018 hearing before Commissioner Jones—a hearing secured jointly by the AMA and California Medical Association. At this hearing, the AMA first to publicly announces its opposition to the merger.

For more information on AMA merger-related advocacy, contact Wes Cleveland, JD, Senior Attorney, at wes.cleveland@ama-assn.org or (312) 464-4503, or Henry Allen, JD, Senior Attorney, at henry.allen@ama-assn.org or (312) 464-4271.

Medicaid

Overview

Debates over Medicaid expansion dominated legislatures again this year with many states seeking ways to counter expanded eligibility with features like work requirements, lock-out periods, time limits and other elements aimed at invoking "personal responsibility" among beneficiaries. In some states, these restrictions represent a necessary compromise to begin or continue Medicaid expansion programs.

2019 Significant activity

Expansion

To date, 36 states and DC have adopted Medicaid expansion and 14 states have not. Policymakers in all three states (ID, NE, UT) that expanded Medicaid via ballot initiative in 2018 sought to scale back the program. The Idaho legislature limited its program to a "partial expansion" meaning the state will expand eligibility only to individuals with incomes up to 100 percent of the federal poverty level (FPL) rather than the 138 percent FPL limit set in the Affordable Care Act. Utah also scaled back the program as passed by voters to a partial expansion. Utah also authorized a cap on enrollment if projected costs exceed appropriations and is seeking a "per capita cap" or limit on federal spending on significant portions of the program. Nebraska pushed back the timeline on its Medicaid expansion program to 2020 and is proposing a tiered program in which beneficiaries would be offered two levels of coverage. All newly eligible beneficiaries would be offered basic coverage but may access "prime" coverage with additional benefits like dental, vision and over-the-counter medications if they engage in care management activities.

In addition to the three states that approved Medicaid expansion via ballot initiative in 2018, policymakers in other states continue to push for expanded eligibility. Georgia passed a law authorizing the governor to seek a waiver for partial expansion up to 100 percent FPL as well, but details on the plan remain sparse. Efforts to expand Medicaid in Kansas and North Carolina, to date, have been unsuccessful. Also, lawmakers in Arkansas and Montana reauthorized Medicaid expansion programs this year.

Work requirements

Medicaid work requirements continue to be a hot topic in legislatures across the country. Both Idaho and Utah added work requirements and other conditions to their programs after voters opted for full Medicaid expansion. Nebraska published a proposal to do so as well. In addition, Montana included work requirements in its law that renewed Medicaid expansion. Specific requirements vary by state but generally require certain beneficiaries to report a certain number of hours of "community engagement activities" in order to maintain

coverage. In addition to employment, beneficiaries can report hours spent in job training or volunteering, for example, to meet the requirements. Certain groups of beneficiaries, such as those that are disabled or full-time caregivers may be exempt from the requirements. Nevertheless, the reporting requirements are expected to be a significant barrier to coverage for low-income patients.

Currently, nine states have approved Medicaid waivers that include work requirements, though only Indiana is currently requiring reporting. Wisconsin and Michigan are scheduled to roll out work requirements in the coming months. Legal challenges have halted work programs in Arkansas and Kentucky. In addition, though Maine received federal approval to implement work requirements, the state is not moving forward with the plan and is instead making vocational training and workforce supports available to Medicaid beneficiaries. Seven other states have waivers pending with the federal government.

Coverage losses from work requirements are certain, though some states have sought to limit the harm. New Hampshire, which has delayed implementation of its work requirements due to projections that tens of thousands of beneficiaries would not comply, enacted a law to halt the work requirement if a substantial number of beneficiaries cannot be contacted, there are not adequate work opportunities available, or transportation or other supportive services are lacking. Montana's work requirement similarly includes a "trigger" requiring the state to reevaluate the work program if more than five percent of the 96,000 low-income adults currently enrolled are dropped from coverage due to not complying with the new work and reporting requirements.

For more information on Medicaid issues, please contact Annalia Michelman, JD, Senior Legislative Attorney, at annalia.michelman@ama-assn.org or (312) 464-4788.

Medical liability reform

Overview

The AMA and our state and specialty society partners continue to advance medical liability reform (MLR) at the state level. State legislatures in 2019 considered bills that promoted a variety of reforms, including expert witness guidelines, affidavit of merit requirements and bills that established processes for early communication and resolution. A couple of states also considered and defeated attempts to raise caps on non-economic damages, while a few states enacted legislation raising the limits of existing caps.

2019 Significant activity

Legislative activity this year includes the successful defeat of legislation to eliminate or raise caps on non-economic damages in Maryland and Oregon; however, a couple of states with existing caps passed legislation to raise their caps. Colorado will now adjust their current cap for inflation every two years starting in 2020. Colorado's cap was previously adjusted for inflation in 1998 and 2008. Maine also enacted legislation increasing their cap on noneconomic damages for wrongful death actions. The bill increases the cap to $750,000 and retains the cap for punitive damages. This was an improvement from the original bill that would have increased the cap to $1,000,000 and eliminated the cap for punitive damages.

In proactive legislation, Kentucky and West Virginia passed strong certificate of merit laws. West Virginia's law also included expert witness guidelines. Colorado enacted an early communication and resolution process and Nevada enacted the Uniform Emergency Volunteer Health Practitioners Act.

For more information on medical liability reform or to pursue any of the liability reforms discussed above, please visit ama-assn.org/go/liability or contact Kim Horvath, JD, Senior Legislative Attorney, at kimberly.horvath@ama-assn.org or (312) 464-4783.

Reversing the nation's opioid epidemic

Overview

In a hopeful change from previous state legislative sessions, there was an increased focus in 2019 on removing barriers to medication-assisted treatment for opioid use disorder. More than 30 states now have arbitrary dose and/or quantity limits on opioid prescribing, but the U.S. Food and Drug Administration (FDA) issued an important clarification about the dangers of abrupt opioid prescribing tapering or discontinuation, and the Centers for Disease Control and Prevention (CDC) issued an important clarification against the use of its 2016 CDC opioid prescribing guideline as a hard threshold policy. To date, however, no state, health insurer or pharmacy has acted to reevaluate or rescind their arbitrary threshold policies. Similarly, legislative or regulatory action is relatively absent to expand access to multidisciplinary pain care, including non-opioid alternatives.

2019 Significant activity

Increasing access to evidence-based care for opioid-use disorder

Thus far in 2019, at least 15 states introduced bills or took other action based on AMA model legislation that eliminates prior authorization for medication assisted therapy (MAT). One of the main ways in which AMA model bills have been used is to introduce the provisions in whole or in part, depending on the individual state need and the political situation in the state. The AMA is working with other states to introduce legislation. A brief snapshot of state activity includes:

- AR – covers the commercial and Medicaid markets (traditional and managed care); signed into law;
- CA – covered the commercial and Medicaid markets—defeated largely because of health insurance company opposition;
- CO – covers the commercial and Medicaid markets; signed into law;
- DC – covers the Medicaid markets; not legislative, but a decision made by the Medicaid director;
- KY – covered the commercial and Medicaid markets—defeated largely because of health insurance company opposition;
- LA – covers the Medicaid markets; awaiting signature;
- ME – covers the commercial and Medicaid markets; pending;
- MO – covers the commercial market;
- MT – covered the commercial and Medicaid markets—defeated largely because of health insurance company opposition;
- NJ – covers the Medicaid markets; signed into law;
- NY – covers the commercial and Medicaid markets; signed into law;
- TX – covers the commercial market;
- VA –covers the commercial and Medicaid markets; signed into law (note: Medicaid already had removed prior authorization in an 1115 waiver program);
- VT – covers the commercial and Medicaid markets; signed into law; and
- WA – covers the commercial and Medicaid markets; signed into law.

It bears highlighting that other states, including North Carolina, removed prior authorization for MAT in Medicaid and are working with the state's major payers, but we have yet to see a public commitment from all North Carolina payers. Similarly, we have been told that Blue Cross in Alabama has removed prior authorization for MAT, but we have not been able to obtain that commitment publicly. Payers in multiple other states, including Rhode Island, Massachusetts and Michigan, to name a few, say that they have stopped requiring prior authorization for MAT, but as noted above, we have not seen public commitment to ending the policy or proof that MAT is available on the lowest cost-sharing tier.

Before 2019, only four states (AZ, IL, MD, PA) had legislation or other initiatives that removed prior authorization for MAT. Thus, while the 2019 activity is positive, payers in more than half the nation have carte blanche to continue policies that delay and deny care to those seeking treatment for an opioid use disorder.

Physician progress to end the epidemic; new AMA Opioid Task Force recommendations

For the past three years, the AMA has measured several aspects where physicians can take action to end the epidemic. Much of this can be traced to the coordinated efforts of the AMA Opioid Task Force (Task Force), which has worked to convene and coordinate organized medicine's response to the epidemic and measure the results. The AMA has issued a report each year highlighting these areas. The topline results from 2018:

- Opioid prescriptions decreased 33 percent between 2013-2018, including more than 12 percent between 2017-2018 alone;
- Use of Prescription Drug Monitoring Programs (PDMPs) increased to more than 450 million in 2018, up from 300 million in 2017 and 61 million in 2014;
- Naloxone prescriptions increased to nearly 600,000 in 2018, up from 136,000 in 2016;
- Physicians and other health care professionals took more than 700,000 courses on opioid prescribing, pain management and related areas in 2018; up from 118,500 in 2015-16; and
- More than 66,000 physicians (and NPs and PAs) are certified to provide in-office buprenorphine; up from 37,000 in 2016.

The progress, however, has not led to a reduction in mortality or a measurable increase in positive patient outcomes. Due to this, the Task Force last month issued new recommendations focused on actions that policymakers must take:

- Remove prior authorization, step therapy and other inappropriate administrative burdens or barriers that delay or deny care for FDA-approved medications used as part of MAT for opioid use disorder.
- Support assessment, referral and treatment for co-occurring mental health disorders as well as enforce state and federal laws that require insurance parity for mental health and substance use disorders.
- Remove administrative and other barriers to comprehensive, multimodal, multidisciplinary pain care and rehabilitation programs.
- Support maternal and child health by increasing access to evidence-based treatment, preserving families and ensuring that policies are nonpunitive.
- Support reforms in the civil and criminal justice system that help ensure access to high quality, evidence-based care for opioid use disorder, including medication-assisted treatment.

"The original task force recommendations called on physicians to accept the responsibility to take a leadership role in ending the epidemic," Patrice A. Harris, MD, MA, President, AMA and Chair, AMA Opioid Task Force, said. "Yet, more people are dying each year, emphasizing the need for policymakers to protect patients' access to evidence-based care for pain and for opioid use disorder."

AMA-Manatt project releases four state-level analyses

The AMA and Manatt Health recently undertook an in-depth analysis of four states' responses to the opioid epidemic: Colorado, Mississippi, North Carolina and Pennsylvania. The analyses focus on state efforts in six key areas to identify best practices and provided a roadmap for all states to take action to increase access to high-quality, evidence-based treatment for persons with a substance use disorder and those who need comprehensive, multidisciplinary, multimodal pain care, as well as increase access to naloxone to save lives from overdose. The analyses also highlight the need to evaluate state-level data and state policies to determine what is working while amending actions and policies that may be having unintended consequences.

Four key themes that emerged from our work:

- **States already have key tools, but must be willing to use them.** State regulators already have considerable authority to pursue policies and changes that can have a significant impact on reducing barriers and improving patient care.
- **Medicaid is leading the way.** Medicaid is on the frontlines and often provides more comprehensive care for substance use disorders than the commercial insurance market, creating opportunities to extend Medicaid successes to commercial coverage. Expanding Medicaid would help even more patients.
- **Grants are helpful, but long-term implementation needs long-term, sustainable funding.** Many best practices that are helping save lives are grant-funded and need long-term, sustainable funding to continue benefiting patients. Without reliable funding streams, programs that help save lives will simply go away.
- **Process of evaluating what works is just starting**. Some states have undertaken efforts to evaluate current policies and programs to determine what is working; most are just beginning. Comprehensive analysis is essential to focus resources on successful interventions—and to revise or rescind policies that are having unintended consequences.

The four state spotlights, available on the AMA opioid microsite, highlight lessons learned from Medicaid directors, insurance commissioners and other state officials, but many of those lessons are relevant for governors, state regulators, attorneys general, federal policymakers and other public and private sector leaders who drive states' responses to the epidemic.

Refocusing the national discussion concerning pain care

There is a growing trend in reports of patients being denied access to opioid therapy. These stories are not new, as the AMA has received them since certain pharmacy chains instituted proprietary opioid analgesic restriction policies dating to 2012-2013, increased following publication of the CDC Guideline for Prescribing Opioids for Chronic Pain in 2016, and further escalated following health insurance company, pharmacy chain and PBM actions to further restrict opioid prescribing. While the stated intent of those policies was to limit the initial opioid prescription for acute pain (typically following minor surgery), the practical effect was for payers, pharmacies and PBMs to reduce or deny opioid therapy to patients, including many with chronic pain, cancer, in hospice or who were receiving palliative care. There also have been growing reports of patients being tapered—consensually or non-consensually—from current opioid doses.

In addition to ongoing AMA advocacy emphasizing the need for individualized patient care and opposing the misapplication of the CDC Guideline, more than 300 physicians sent a letter to CDC highlighting reports of patient harm, including suicides.

FDA and CDC issue clarifications; HHS Task Force issues highly positive pain care report

In response these increasing reports of patient harm from the opioid restriction policies and non-consensual tapering, the FDA and CDC have recently made significant statements to mitigate patient harms.

On February 28, 2019, the CDC sent a letter to the National Comprehensive Cancer Network, American Society of Clinical Oncology and American Society of Hematology noting that, "The [CDC opioid prescribing] Guideline is not intended to deny any patients who suffer with chronic pain from opioid therapy as an option for pain management," and that "CDC encourages physicians to continue to use their clinical judgment and based treatment on what they know about their patients, including the use of opioids if determined to be the best course of treatment."

On April 9, 2019, the FDA issued a statement emphasizing that it is "requiring changes to the prescribing information for these medicines that are intended for use in the outpatient setting. These changes will provide expanded guidance to health care professionals on how to safely decrease the dose in patients who are physically dependent on opioid pain medicines when the dose is to be decreased or the medicine is to be discontinued."

Then on April 24, 2019, the *New England Journal of Medicine* published a CDC "Perspective" in which the authors of the 2016 CDC Guideline said that "[e]fforts to implement prescribing recommendations to reduce opioid-related harms are laudable. Unfortunately, some policies and practices purportedly derived from the guideline have in fact been inconsistent with, and often go beyond, its recommendations." The authors went on to note multiple ways in which the guidelines have been misinterpreted as inflexible standards, including support for individualized patient care: "Policies should allow clinicians to account for each patient's unique circumstances in making clinical decisions."

The AMA welcomed the CDC's revised view of the guidelines, emphasizing that while the AMA continues to encourage judicious prescribing decisions, "the guidelines have been misapplied so widely that it will be a challenge to undo the damage."

Finally, on May 9, 2019, the U.S. Department of Health and Human Services Pain Management Best Practices Inter-Agency Task Force (HHS Task Force) issued its final "Report: Updates, Gaps, Inconsistencies, and Recommendations."

The AMA strongly backed the comprehensive, common-sense proposals in the final report for sending a clear signal to the physician community about the treatment required for patients in pain. Specifically, AMA analysis found critical balance to effectively manage patients' pain while also advancing policies to end the epidemic of opioid-related deaths.

Among the HHS Task Force recommendations:

- Bolstering support for multidisciplinary, multimodal approaches to treating patients with acute and chronic pain;
- Reversing harmful policies such as arbitrary limits on prescribed pain medications;
- Providing individualized treatment that accounts for co-morbidities and severity, not one-size-fits-all approaches—a point emphasized recently by the Centers for Disease Control and Prevention;
- Encouraging better health insurance coverage of affordable, evidence-based non-opioid medications and non-pharmacologic treatments for pain and eliminating obstacles to treatment such as fail-first policies;
- Recognizing the urgent need to address stigma as a barrier to care.

The AMA will continue to promote the HHS task force recommendations.

For more information about the Task Force and any other areas mentioned above, please contact Daniel Blaney-Koen, JD, Senior Legislative Attorney, at daniel.blaney-koen@ama-assn.org or (312) 464-4954.

Private payer reform

Overview

The way in which patients and physicians experience the private health care system can be frustrating to say the least. The Advocacy Resource Center continues to work with state and national medical specialty societies to enact state legislation that helps support physicians and patients in all aspects of their relationships with health insurers and other third-party payers. Several states had success this year enacting important reforms. Others continued the fundamental process of laying the groundwork and educating lawmakers about the importance of simplifying, streamlining and increasing the transparency of physician-payer interactions for the benefit of all stakeholders.

In addition to supporting state legislative efforts, the AMA also continued its work with the National Association of Insurance Commissioners (NAIC), National Conference of Insurance Legislators (NCOIL) and other national groups to promote changes to the way commercial health plans interact with patients and their physicians.

2019 Significant activity

Balance billing

There have been major developments at both the state and federal level this year in terms of so-called "surprise billing" legislation. While almost two dozen state legislatures introduced surprise billing legislation this year, federal activity on the issue has halted or slowed much of those state efforts. That being said, a handful of states have moved ahead and enacted surprise billing laws this year.

State activity

So far in 2019, more 40 bills in 20 states related to surprise billing were introduced and many remain in play. Not unlike in Washington, DC, often state surprise billing legislation is one of the few bipartisan healthcare issues that state policymakers can tackle. Five of the more broad and impactful new laws are summarized below.

Washington

Under the new law, a balance billing ban applies to emergency services, as well as non-emergent services at an in-network hospital or ambulatory surgical facility if the services involve surgical or ancillary services. Plans must also "hold enrollees harmless from balance billing" for emergency services that are provided by out-of-network hospitals in states that border Washington.

Physicians and other providers are paid directly by the plans at a "commercially reasonable rate" and the Insurance Commissioner is directed to procure a data set to help define "commercially reasonable." That data set must be compiled in consultation with providers, facilities and carriers and reviewed by an advisory committee of the same stakeholders.

To dispute a payment, an out-of-network provider or facility must notify the plan within 30 calendar days and this begins a 30-day informal negotiation period. If the parties cannot reach an agreement, either party may initiate binding arbitration. Claims can be bundled over a two-month period.

The arbiter must consider:

- Evidence submitted by the parties in support of their positions;
- Patient characteristics and the circumstances and complexity of the case, including time and place of service and whether the service was delivered at a level I or level II trauma center or a rural facility that are not already reflected in the provider's billing code for the service; and
- The data set compiled from the Washington all payer claims database (APCD) that includes claims for median in-network amounts, median out-of-network allowed amounts and median billed charges for the same or similar services in a geographic area. Once compiled, the data set is adjusted in subsequent years by applying the consumer price index-medical component.

Federally regulated plans can opt-in to complying with the law and additional provisions provide some improvements to network adequacy requirements and address cost transparency.

Texas

Under the new Texas law, out-of-network providers cannot bill a patient for more than an applicable copayment, coinsurance or deductible based on the amount initially determined payable by plan or, if applicable, a modified amount as determined under the issuer's internal dispute resolution process.

Out-of-network physicians are paid and undefined usual and customary rate and if dissatisfied with the payment, either party can initiate binding, baseball-style arbitration. The determination would have to take into account several factors including:

- Whether there is a gross disparity between the fee billed by the out-of-network provider and:
    - fees paid to the out-of-network provider for the same services or supplies rendered by the provider to other enrollees for which the provider is an out-of-network provider; and
    - fees paid by the health benefit plan issuer to reimburse similarly qualified out-of-network providers for the same services or supplies in the same region;
- The level of training, education and experience of the out-of-network provider;
- The out-of-network provider's usual billed charge for comparable services or supplies with regard to other enrollees for which the provider is an out-of-network provider;
- The circumstances and complexity of the enrollee's case, including the time and place of the provision of the service or supply;
- Individual enrollee characteristics;
- The 80th percentile of all billed charges for the service or supply performed by a health care provider in the same or similar specialty and provided in the same geozip area as reported in an independent benchmarking database;
- The 50th percentile of rates for the service or supply paid to participating providers in the same or similar specialty and provided in the same geozip area as reported in an independent benchmarking database;
- The history of network contracting between the parties; and
- An offer made during a required informal settlement teleconference.

The arbiter must give a decision within 75 days and would determine whether the billed charge or initial payment made by the health benefit plan issuer or administrator was closest to the reasonable amount for the services or supplies.

New Mexico

Under the new law, patients are only responsible for in-network cost sharing when they receive emergency care from an out-of-network provider *or* when they receive non-emergency out-of-network care at an in-network hospital where in-network care was unavailable; an out-of-network provider renders unforeseen services; or an out-of-network provider renders services for which the patient did not give specific consent. The payment rate to out-of-network physicians in these situations is calculated using claims data reflecting the allowed amounts in the 2017 plan year. Specifically, under the bill, "surprise bill reimbursement rate" means the 60th percentile of the allowed commercial rate for a health care service performed by a provider in the same or similar specialty in the same geographic area, as reported in a benchmarking database maintained by a nonprofit organization. A last-minute addition to the law provided that no reimbursement rate would be paid at less than 150 percent of the 2017 Medicare reimbursement rate.

Nevada

The Nevada law protects patients from surprise bills for emergency care by holding them responsible for only the in-network cost sharing. Under the benchmark payment provisions for out-of-network physicians and health care providers:

- If the out-of-network emergency provider had a contract with the health plan within the last 12 months, and terminated the contract without cause, the health plan is required to pay the provider the amount that would have been paid for the services under the contract.
- If the out-of-network provider had a contract with the health plan in the last 12 months and terminated the contract for cause, or if the insurer terminated the contract without cause, the health plan is required to pay the provider 108 percent of the amount that would have been paid for the services under the contract.
- If the health plan terminated a contract within the last 12 months for cause, the plan is required to pay the provider an amount that the plans determines to be fair and reasonable.
- If the contract (within the last 12 months) was not terminated by either party, the health plan must pay the most recent contract rate with an inflationary increase.

If no contract existed between the parties in the last 12 months, the plan submits an offer to the out-of-network provider. The provider can accept the payment or request an additional amount. If the payer rejects the requested amount, the provider can initiate binding, baseball-style arbitration. The provider and plan can submit any relevant information to assist the arbiter in making a determination.

The bill also provides for small claims arbitration – an expedited process for disputed amounts under $5,000– as well as for reporting requirements on the impact of the legislation on the market.

Colorado

Under the new law, patients cannot be billed beyond the in-network cost sharing when they receive out-of-network care at an in-network facility or out-of-network emergency care, and plans must pay the out-of-network provider directly. Payments made by patients are applied to in-network cost-sharing limits.

For out-of-network care provided at an in-network facility where the patient does not voluntarily use an out-of-network provider, or for out-of-network emergency care provided at an out-of-network facility, the insurer is required to pay the health care professional the greater of (1) 110 percent of the insurer's median in-network rate for that service in the same geographic area, or (2) the 60th percentile of the in-network rate for the same service in the same are for the prior year based on commercial claims data from the state APCD.

If a patient receives emergency services at an out-of-network facility (other than those operated by the Denver Health and Hospital Authority) the facility receives the greater of (1) 105 percent of the insurer's median in-network rate or (2) the median in-network rate for the same service provided in a similar facility or setting in the same geographic area of the prior year based on claims data from the state APCD. Of note, a provider can request that the Commissioner look into whether a plan is complying with the payment requirements.

Additionally, if the provider believes that a payment is insufficient, they may initiate an arbitration process. A standard arbitration form will be developed and each party must submit their final offer and the arbiter picks one of the offers. The arbiter must consider the circumstances and complexity along with the provider's level of training, education, experience and specialization and the previously contracted rate if a contract existed between the two parties within the last year.

Federal activity

At the federal level, the Senate Health, Education, Labor and Pensions (HELP) Committee has marked up S. 1895, the Lower Health Care Costs Act, which included provisions related to protecting patients from surprise medical bills. Unfortunately, the legislation would set payments for unanticipated out-of-network care at the plan-specific median in-network rate and fails to incorporate an arbitration process for physicians to challenge the payment. Committee Chair Lamar Alexander (R-TN) also made a commitment to continue working with members, including Senator Bill Cassidy, MD (R-LA), to address their concerns about the lack of an arbitration model to address payment disputes.

Legislation has also passed out of the House Energy and Commerce Committee that would set payment rates at the 2019 median in-network rates with an inflationary increase each year. During the full committee mark-up, an amendment was successfully offered by Congressmen Raul Ruiz, MD (D-CA) and Larry Bucshon, MD (R-IN) to add an arbitration process to the legislation that would allow certain payment disputes beyond a threshold to proceed to arbitration. While the arbitration process outlined in the committee bill is still problematic (e.g. the arbiter cannot consider charged rates), it is a positive step toward a fairer process. Two additional House Committees also have jurisdiction – Education and Labor and Ways and Means – and will likely be taking up this issue soon.

The AMA and state and specialty medical societies continue to advocate for legislation that will protect patients from unanticipated out-of-network bills while encouraging insurers to come to the negotiating table and offer fair contracts.

Prior authorization and step therapy

There continues to be every indication that prior authorization requirements are increasing and expanding. Physician are troubled and frustrated by the overstepping of insurers into the clinical decision-making process and with the time, money and energy spent on ensuring their patients can access covered drugs and services.

The AMA again released its Prior Authorization Physician Survey earlier this year, and of the practicing physicians surveyed:

- 65 percent report waiting at least one business day for a decision and 26 percent reported waiting at least 3 business days;
- 91 percent report care delays associated with prior authorization;
- 75 percent report that prior authorization can lead to treatment abandonment;
- 91 percent report that prior authorization can have a negative impact on patient clinical outcomes.
- 86 percent of physicians say the prior authorization burden is high or extremely high; and

- Physicians and their staff are spending an average of two business days each week competing prior authorization.

But perhaps most concerning was that 28 percent of respondents reported that prior authorization has led to a serious adverse event for their patients.

It is no surprise that there were nearly 85 bills in the state legislatures this year addressing utilization manage, and in several states (e.g. CO, KY, MD, ME, MO, NM, TX, VA, WV) medical societies were able to enact prior authorization legislation despite facing strong opposition from insurers and their local trade associations.

The AMA also recently revised its prior authorization model bill to incorporate many of the provisions that states have debated and some have enacted over the last several years. New provisions include:

- Requiring that only physicians of the same or similar specialty and licensed in the state where the health care service will be provided are able to make adverse determinations for the plans;
- Requiring that prior to an adverse determination based on medical necessity, the ordering physician has the opportunity to discuss the medical necessity of the health care service with the physician who will be responsible for issuing a determination;
- Guaranteeing that a change in dosage of a prescription medication does not trigger a new prior authorization requirement;
- Establishing that individuals with chronic conditions only need to obtain prior authorization once for the health care services needed to treat their conditions;
- Ensuring that when patients change plans, authorizations follows them and are valid for at least the first 60 days of their new coverage; and
- Preventing a change in coverage or approval criteria by the plan from impacting a patient's authorization.

For more information on the Advocacy Resource Center's private payer reform campaign, please visit ama-assn.org/go/arc or contact Emily Carroll, JD, Senior Legislative Attorney, at emily.carroll@ama-assn.org or (312) 464-4967.

Public health

Overview

As with most years, 2019 was an active year for public health with states taking up a wide range of bills to legislate the public health, public safety and the patient-physician relationship.

2019 Significant activity

Vaccines

With the number of measles cases reaching the highest levels in more than 25 years, vaccine exemptions were a hot topic in states across the country. Several sought to eliminate all nonmedical exemptions to the childhood immunizations required for parents to enroll children in school, and such legislation was enacted in Maine and New York. These two states join California, Mississippi and West Virginia to bring the total count of states that prohibit all nonmedical exemptions comes to five. Currently, 45 states and DC permit religious exemptions to mandatory childhood immunizations and 15 permit personal or philosophical exemptions. In addition to the progress made in the northeast, Washington also strengthened its vaccine laws, barring

personal and philosophical objection to the measles, mumps and rubella vaccine. Legislation in Oregon that would have barred nonmedical exemptions made significant progress but ultimately did not pass. Legislation that would have discourage immunization rates was defeated in several states. Notably, Arizona defeated three high-profile anti-vaccination bills.

Women's health

State abortion-related bills reignited a national debate about abortion this year. Five states (GA, KY, LA, MS, OH) passed laws banning the procedure after a fetal heartbeat is detected. Alabama banned nearly all abortions; Missouri banned abortion after 8 weeks; Arkansas and Utah after 18 weeks. These laws are being challenged in federal courts and, to date, none have gone into effect. Four states (AR, KY, ND, OK) enacted laws requiring abortion providers to falsely inform patients that their abortion may be "reversed." Abortion "reversal" legislation was also vetoed in Kansas. Governors in Montana and North Carolina vetoed bills that placed requirements on the care of infants born after failed abortions with criminal penalties for physicians; however, similar legislation was signed in Texas.

On the other end of the spectrum, four states (IL, NY, RI, VT) enacted legislation codifying and affirming the right to abortion. Nevada also repealed its criminal abortion law, eliminating the mechanism for prosecuting abortion providers if *Roe v. Wade* is overturned. In addition, Maine passed legislation requiring the state Medicaid program to cover abortion services.

Firearms

2019 continued the momentum of 2018 and saw many successes with laws to prevent gun violence. Four states (CO, HI, NY, NV) passed laws authorizing extreme risk protection orders (sometimes called "Red Flag laws"). Connecticut expanded safe storage requirements in the home. California approved a first-in-the-nation requirement that anyone purchasing ammunition must undergo a background check. Washington, New Mexico and Nevada strengthened background check requirements, and several states closed loopholes that enable domestic abusers' access to firearms, including North Dakota, New Mexico and Washington.

Tobacco

This year ten states (AR, CT, DE, IL, MD, TX, UT, VA, VT, WA) raised the minimum age to purchase tobacco products to 21 from 18, bringing the total number of Tobacco 21 states to 17 plus DC.

LGBTQ patients

Four states (CO, MA, ME, NY) passed laws prohibiting the practice of so-called "conversion therapy" on minors. "Conversion therapy" refers to interventions that attempt to change an individual's sexual orientation or sexual behaviors. Eighteen states and DC now prohibit the harmful practice.

For more information on this Advocacy Resource Center campaign, please contact Annalia Michelman, JD, Senior Legislative Attorney, at annalia.michelman@ama-assn.org or (312) 464-4788.

Scope of practice

Overview

State legislatures in 2019 considered over 1,000 bills seeking to eliminate team-based care models of health care delivery and/or expand the scope of practice of non-physician health care professionals. For example, nurse practitioners continued to seek independent practice authority and to chip around the edges of state law.

Physician assistants were more emboldened this year to seek independent practice with the adoption of the optimal team practice act by the American Academy of PAs (AAPA) last year, and pharmacists sought prescriptive authority in at least a dozen states. While these three groups of non-physician health care professionals accounted for the vast majority of scope bills this year, hard fought battles also occurred in a number of states with optometrists seeking surgical authority, naturopaths seeking licensure and psychologists seeking prescriptive authority. With tough fights in all cases, most bills that threatened passage were defeated, often with the support of the Advocacy Resource Center and – as is often the case with scope bills – a coordinated state and specialty effort.

That said, a couple scope bills did pass. Arkansas passed legislation that allows optometrists to perform surgery. This fight, however, is not over as works are underway to place a referendum on the 2020 ballot, allowing voters to have the final say. This approach will send a clear message to optometrists that the house of medicine does not take these expansions lightly and will seek all available remedies to protect patients. Psychologists prescribing bills were defeated in a number of states, but a few states that already allow psychologist to prescribe expanded their existing laws. New Mexico now allows nurse practitioners, psychiatric nurse practitioners and clinical nurse specialists to supervise a prescribing psychologist. Illinois passed legislation as well, but the final version included many important amendments that greatly limited the final scope of the bill. In the final version prescribing psychologists may include their name on the medications they prescribe, can participate in telepsychiatry and must complete 14 months of full-time clinical rotations.

Following is a summary of the legislative activity for advanced practice registered nurses (APRNs), physician assistants and pharmacists.

2019 Significant activity

Advanced practice registered nurses

APRNs continue to aggressively advocate for independent practice in states across the country. We are also seeing states introduce legislation that would allow nurse practitioners to directly bill insurers, establish pay parity with physicians, receive hospital privileges, be considered a “medical director,” and sign certificates, documents, or forms that were previously only allowed to be signed by a physician. Many states also considered legislation that would expand an APRNs prescriptive authority, such as allowing nurse practitioners to prescribe controlled substance and/or prescribe independently. Many states also considered legislation that would allow nurse practitioners to prescribe controlled substances as part of an opioid treatment program. These types of bills continue to be a challenge for state medical associations and national specialty societies altogether, but they are often able to negotiate important concessions. For example, in Arkansas legislation was enacted that allows APRNs to prescribe schedule II controlled substances, but prescriptions for opioids are limited to a 5-day supply and prescriptions for stimulants must have been initiated by a physician for the same condition and the physician must have evaluated the patient within six months before the APRN issued the prescription. Similarly, Louisiana passed legislation allowing APRNs to provide MAT as long as the APRN’s collaborating physician is authorized to provide MAT. Oregon further expanded a APRNs prescriptive authority, removing the 10-day limit for schedule II-V controlled substances prescribed by CRNAs. In Utah, legislation was enacted that amended requirements for ARPN prescriptive authority for schedule II controlled substances. The APRN must prescribe in accordance with a consultation and referral plan if the APRN is practicing in an independent solo practice and has been licensed for less than 2,000 hours or less than one year; or owns or operates a pain clinic. An APRN with at least three-years of experience as a APRN may supervise a consultation and referral plan.

Independent practice bills were introduced in a number of states. While state medical associations continue to feel pressure from lawmakers to compromise on these bills, legislation that would have granted independent practice to APRNs was defeated in four states (CA, FL, IN, MS).. A couple of states enacted legislation that modify requirements for collaborative practice arrangements. For example, Texas replaced face to face meetings between APRNs and physicians with periodic meetings that occur at least once a month in a manner determined by the physician and APRN.

The Advocacy Resource Center continues to work with state and specialty societies to address APRN issues and promote physician-led team based care.

APRN Multistate Licensure Compact

The APRN Multistate Licensure Compact (APRN Compact) which was created by the National Conference of State Boards of Nursing (NCSBN) is in effect dead. Due to the effective collaborative efforts of the AMA, state medical associations and national specialty societies, the APRN Compact has been defeated in every state in which it was introduced in 2018 and 2019. The NCSBN has revisited the APRN Compact language and is in the process of revising. We will closely monitor this process.

Physician assistants

Physician assistants were more emboldened this year to seek scope expansions with the release of the model legislation and regulation by the AAPA last year that supports independent practice, the "optimal team practice (OTP) act." Elements of the OTP act were found in several state bills, but no states sought to enact the OTP act in its entirety. Many states saw bills that attempted to chip away at direct physician supervision generally and/or allow physician assistants to perform certain functions without physician supervision. Most bills were soundly defeated or amended to reflect minimal change in practice. However, a few bills passed.

For example, North Dakota passed legislation that requires physician assistants to practice within a collaborative practice agreement for the first 4,000 hours of practice. After this time, physician assistants may practice without a collaborative practice agreement in certain types of facilities, including a licensed health care facility with a credentialing and privileging system, physician-owned facility or practice, or facility or practice approved by the board of medicine. Colorado passed legislation that still requires direct supervision, but stair steps the supervision requirements based on the number of years a physician assistant has been in practice. If the physician assistant changes his or her scope of practice or primary practice area, they must repeat the process. Furthermore, Louisiana now allows physician assistants to provide MAT as long as the physician assistant's supervising physician is authorized to provide MAT. Finally, West Virginia passed legislation that allows physician assistants practicing in a hospital to submit a notification in writing to the board that the physician assistant will work in collaboration with one or more physicians in a hospital. In all other practice environments, a written collaborative practice agreement between a physician assistant and collaborating physician must still be filed with and approved by the board of medicine.

Pharmacists

This session the Advocacy Resource Center tracked over 100 pharmacists related bills in 29 states, ranging from expanding pharmacists' authority to administer vaccines to bills that allow pharmacists to prescribe medications outside of a collaborative drug therapy agreement with a physician. Overall about a dozen states had bills that expand pharmacists' prescriptive authority, including bills that would allow pharmacists to prescribe medications for hormonal contraceptives, smoking cessation therapy, travel medication, emergency refills, minor conditions and/or conditions that can be diagnosed or confirmed with a CLIA waived test.

Of these bills, the most concerning are those that allow pharmacists to prescribe medications for minor conditions. This is often tied to the ability to diagnose or confirm the condition with a CLIA waived test, such as a test to confirm streptococcus or influenza. Of the handful of states with these types of prescribing bills (AZ, FL, ID, NY, TX), all of them were defeated except Idaho. Idaho's new law (HB 182) allows pharmacists to independently diagnose and prescribe drugs to patients for conditions that in the pharmacist's judgement:

- Do not require a new diagnosis;
- Are minor and generally self-limiting;
- Have a CLIA waived test used to guide diagnosis or clinical decision making; OR
- Threatens the health or safety of the patient if a prescription was not immediately dispensed.

As enacted, the bill removes language that required the Idaho Board of Pharmacy (BOP) to authorize conditions for which pharmacists may prescribe. While far from perfect, this previous law, which was enacted in 2017 despite strong opposition from the AMA and Idaho Medical Association (IMA), limited pharmacist prescriptive authority to specific conditions authorized by the BOP and approved by the legislature. This regulatory process at least afforded the physician community the opportunity to comment on conditions prior to approval by the BOP and resulted in some important patient safety provisions. This new law essentially allows pharmacists independent prescriptive authority.

For more information on these and other scope of practice legislative activity, including the Scope of Practice Partnership, please contact Kim Horvath, JD, Senior Legislative Attorney, at kimberly.horvath@ama-assn.org or (312) 464-4783.

Telemedicine

2019 Significant activity

This year, several states took steps to increase access to telemedicine, including, Texas which expanded coverage of telemedicine to Medicaid managed care plans and South Dakota, which expanded private payer coverage of telemedicine. A number of states also sought pay parity for telemedicine services. For example, Utah established pay parity for telemedicine services provided by Medicaid, while Texas enacted legislation similar to AMA's model bill to establish pay parity for telemedicine services for private payers. California also has similar legislation pending, including language that prohibits health plans from limiting telemedicine services to third party corporate entities.

In addition, South Dakota adopted legislation that, among other things, confirmed that a patient-physician relationship can be formed via telemedicine and that a physician must hold a license to practice medicine in the state to treat the patients of that state.

Finally, Virginia expanded the definition of telemedicine to include remote patient monitoring services used to enhance the delivery of home health care, including monitoring of clinical patient data such as weight, blood pressure, pulse, pulse oximetry, blood glucose and other condition-specific data; medication adherence monitoring; and interactive video conferencing with or without digital image upload.

Notably, the Advocacy Resource Center recently updated our telemedicine model bill to include language prohibiting health plans from limiting telemedicine coverage to third party corporate entities. This language was added in response to concerns raised that certain health plans were not covering telemedicine services provided by in-network physicians, instead directing patients to third party corporate entities with whom the patient had no prior patient-physician relationship. If you would like additional information about the AMA

model bill, please contact Kim Horvath, JD, Senior Legislative Attorney at kimberly.horvath@ama-assn.org or (312) 464-4783.

Interstate Medical Licensure Compact

The Interstate Medical Licensure Compact (the Compact) continued to make gains in 2019 with Georgia, Kentucky, North Dakota and Oklahoma passing legislation to join the Compact. This brings the total number of states in the Compact to 29 (AL, AZ, CO, GA, ID, IA, IL, KS, KY, MD, ME, MI, MN, MS, MT, NE, NV, ND, NH, OK, PA, SD, TN, UT, VT, WA, WI, WV, WY), plus DC and Guam.

The Compact was officially launched in 2017 and started accepting applications for licensure at imlcc.org. Currently, 21 of Compact member states can serve as the primary state of licensure and source of verification. The remaining states are setting the groundwork for the ability to conduct background checks. Legislation to enable or reaffirm this authority is moving quickly.

The Advocacy Resource Center will be working to ensure that the Compact continues to gain steam in 2020, as the Compact's promise of license portability will best be realized if every state and territory are members. For more information on telemedicine and the Compact, please visit ama-assn.org/practice-management/digital or contact Kim Horvath, JD, Senior Legislative Attorney, at kimberly.horvath@ama-assn.org or (312) 464-4783.