State Legislative Advocacy

The FMA remains focused on preparations for the 2020 Florida Legislative Session, which will begin on Tuesday, Jan. 14. Following is a summary of notable developments from recent legislative committee meetings in Tallahassee:

- HB 309, filed by Rep. Ralph Massullo, MD, passed out of its first committee on Nov. 13. This bill would prohibit non-physician healthcare providers from using any descriptor that would imply their ability to practice allopathic or osteopathic medicine. Only a physician licensed under chapter 458 or 459 would be able to refer to himself or herself as a "physician," or as a specialist such as a cardiologist, anesthesiologist, radiologist, etc. The vote was 12-2 with only Rep. Tracie Davis and Rep. Carlos Guillermo Smith voting against the bill.


- Legislation has been filed that would prohibit retroactive denials when prior authorization has been granted, prohibit insurers from imposing additional prior authorization requirements for specified procedures, and prohibit certain step-therapy practices while instituting a physician override process.

- The above insurance reforms probably will be tied to legislation that would prohibit unfair practices by Pharmacy Benefit Managers (PBMs) and increase transparency.
Federal Legislative and Regulatory Advocacy

• The FMA has taken an increasingly active role in advocating on behalf of physicians at the federal level. This year, the FMA retained a lobbying firm in Washington, D.C., and FMA physician leaders have participated in three D.C. fly-ins to make sure Florida physicians’ voices are heard by members of our state’s congressional delegation.

• The FMA also remains active with several coalition groups representing physicians’ interests at the federal level, including the Coalition of State Medical Societies and the Partnership to Empower Physician-Led Care.

• The FMA has been working closely with several national specialty societies on the issue of out-of-network payment (also called “surprise billing”). This remains our top federal priority.

• We are closely monitoring and evaluating the Trump Administration’s recently unveiled Transparency in Coverage Proposed Rule.

• If finalized, this rule would require all non-grandfathered group health insurance plans and all health insurance issuers offering non-grandfathered health insurance coverage in the individual and group markets to establish an online tool, and in paper form upon request, for enrollees to get estimates of their personalized out-of-pocket costs for all covered healthcare items and services. This is to allow consumers to compare costs and shop among different providers prior to the receipt of care. Specifically, seven content elements would be required to be disclosed in plain language:

1. Estimated cost-sharing liability
2. Accumulated amounts with respect to any deductible or out-of-pocket limit/max
3. Negotiated rates for an in-network provider
4. Out-of-network allowed amounts for an out-of-network provider
5. List of the items and services for which the cost-sharing information is being disclosed
6. Notice of any prerequisites of coverage, such as prior authorization or step therapy
7. Disclosure notice explaining to the consumer that out-of-network providers may balance bill, that actual charges may differ, that the estimate is not a guarantee of coverage, and any additional information or disclaimers that the plan feels is necessary
In addition, the proposed rule would require these health insurance plans to make publicly available (not just to enrollees) two machine-readable files with all of their in-network negotiated rates with providers (the “Negotiated Rate File”), as well as historical payments of allowed amounts to out-of-network providers (the “Allowed Amount File”). Such files would be required to be updated monthly. These files must include three content elements:

1. Name or identifier for each plan option or coverage
2. Billing codes
3. Negotiated rates (including the last date of the contract term) or historical out-of-network allowed amounts (during the 90-day time period that begins 180 days prior to the publication date of the Allowed Amount File)

The proposed rule would encourage health insurance plans to share savings with enrollees who choose lower-cost, higher-value providers by allowing plans to take credit for shared savings payments in their medical loss ratio (MLR) calculations.

The proposed rule also includes two requests for information (RFI):

1. Whether these health insurance plans should also be required to make the cost-sharing information above available through a standards-based application programming interface (API)
2. How healthcare quality information can be incorporated into the price transparency proposals

Comments are due 60 days from publication in the Federal Register. If finalized, the proposed rules would become effective one year after the finalization of the rule, except for the MLR proposal, which would be effective beginning with the 2020 MLR reporting year.

This proposal is highly controversial and sure to receive intense scrutiny from health plans and provider organizations alike.

The FMA plans to publish additional information regarding the proposed regulation in an upcoming edition of FMA News. We encourage our members to send us their feedback about the proposal’s potential effects. Rest assured that we will work closely with our partners in medicine to evaluate this proposal and its possible impact on physicians.
FMA Events
- 2019-20 FMA Karl M. Altenburger, MD Physician Leadership Academy second session — Dec. 6-7, Gainesville
- FMA Board of Governors winter meeting — Jan. 17-19, Hilton Orlando
- Florida mandatory CME live event — Jan. 18, Hilton Orlando. Click here to register.

FMA President’s Travel Schedule
AMA Interim Meeting — Nov. 16-19, San Diego
Dade County Medical Association Board Meeting – Nov. 26, Miami
FMA Physician Leadership Academy – Dec. 5-6, Gainesville
Florida Plastic Surgeons Forum Meeting – Dec. 14-15, Palm Beach
Congressional Activity

H.R. 3 Stalls in the House as Pro-Generic Bills Advance; Revised Senate Finance Committee Drug Pricing Bill Expected

Although it was expected that H.R. 3—the Speaker Pelosi-led “Lower Drug Prices Now Act of 2019”—would see a November vote in the House of Representatives, continued difficulty in securing a full score of the bill from the Congressional Budget Office (CBO) has stalled its progress. In the meantime, the House Energy & Commerce (E&C) Committee and House Judiciary Committee advanced several patent reform bills aimed at increasing generic competition as a means to reducing drug prices.

On November 13, the House E&C Health Subcommittee passed H.R. 2387, the “Stop the Overuse of Petitions and Get Affordable Medicines to Enter Soon (STOP GAMES) Act”, a bill that would enhance the Food and Drug Administration’s (FDA) authority to dismiss “anti-competitive” citizen petitions deemed to delay the market entry of generic drugs. H.R. 2387 awaits further action by the full E&C Committee. On November 20, the full House Judiciary Committee passed two bills: H.R. 3991, the “Affordable Prescriptions for Patients through Improvements to Patent Litigation Act of 2019”; and H.R. 5133, the “Affordable Prescriptions for Patients through Promoting Competition Act of 2019”. H.R. 3991 is aimed at discouraging the practice of so-called “patent thicketing” by limiting to 20 the number of patents a brand manufacturer may assert in any patent litigation. H.R. 5133 would prohibit the practice of “product hopping”, wherein a brand manufacturer makes nominal changes to a drug for the purpose of extending its exclusivity period and blocking generic competition. A companion bill to both H.R. 3991 and H.R. 5133 (S. 1416) passed out of the Senate Judiciary Committee in June.

In the Senate, Finance Committee Chairman Grassley (R-IA) continues to work to build support for his drug pricing bill S. 2543, the “Prescription Drug Pricing Reduction Act,” which passed out of the Finance Committee earlier this year. In a speech on November 21, Grassley touted CBO’s score of S. 2543, which estimates over $100 billion in taxpayer savings, $6 billion in reductions to Part D premiums, and $25 billion in reductions to beneficiaries’ out-of-pocket (OOP) costs. Grassley also defended the bill’s inclusion of inflationary rebate penalties for Part B and Part D drugs, and announced that he and Ranking Member Wyden (D-OR) would soon release a revised version of S. 2543 that would include additional flexibility for beneficiaries to smooth high upfront OOP costs and permit more negotiated savings to pass through to beneficiaries at the pharmacy counter. These revisions are designed to attract more bipartisan support for the bill, which saw nine Republican defections during its Committee consideration.

Senate HELP Committee Holds Confirmation Hearing for FDA Commissioner Nominee

On November 20, the Senate Health, Education, Labor & Pensions (HELP) Committee held a hearing on President Trump’s nominee to be FDA Commissioner, Dr. Stephen Hahn. Dr. Hahn, a practicing radiation oncologist, currently serves as Chief Medical Executive at the University of Texas MD Anderson Cancer Center. The hearing revealed a variety of Dr. Hahn’s priorities, including:

- On generic drug safety: agreement on the need to improve the safety of generic medicines, particularly those manufactured overseas;
- On opioids: support for stricter FDA oversight of opioid packaging and labeling rules, accelerated approval of non-opioid alternatives, and increased advocacy for a holistic methodology for pain management;
- On drug development: an understanding of the immense promise of the coming generation of medicines, and an interest in and excitement for “new and improved ways of evaluating data” that might help regulators do their jobs more efficiently;
On drug pricing: support for more transparency and competition as the primary methods for reducing prices;

On drug importation: support for “moving forward with action that makes sense,” a statement he followed up by underscoring the FDA’s primary goal of ensuring patient safety. He espoused a similar view (the importance of balancing patient need with patient safety) in an exchange on the use of cannabidiol (CBD) to treat child seizure disorders.

HELP Committee Chairman Alexander (R-TN) plans to hold a formal Committee-level nomination hearing on December 3, his hope being that full Senate consideration could then take place by the end of the year.

**Surprise Billing Compromise Discussions Continue**

The Chairs and Ranking Members of the key Committees of jurisdiction on surprise medical billing continue to work toward a compromise bill that could be wrapped into an end-of-year spending package. On November 18, House E&C Ranking Member Walden (R-OR) touched on the topic at a White House briefing, indicating that a compromise bill was close at hand. Walden emphasized strong support from voters for protecting patients from surprise medical bills, as well as CBO’s estimate that such a policy would save billions of dollars that the government could then use to fund a longer-term budget package at the end of the year.

**Impeachment and Government Funding Continue to Complicate Matters**

Impeachment proceedings against President Trump transitioned into the public hearing phase in November, with myriad public officials providing testimony to the House Intelligence Committee over the latter half of the month. Democrats have now begun to draft their report, which will form the basis for the drafting of any Articles of Impeachment by the House Judiciary Committee, which is expected to hold additional hearings after the Thanksgiving break. On the Senate side, Senate Judiciary Chairman Graham (R-SC) has opened an inquiry into Hunter Biden (son of former Vice President and current Democratic Presidential hopeful Joe Biden) on the question of his involvement in the firing of a Ukrainian prosecutor that was investigating a company on whose Board of Directors the younger Biden sat. Notwithstanding the partisan rancor surrounding Congress during these impeachment activities, lawmakers were able to pass another short-term deal to keep the government funded through December 20. A long-term budget deal or another short-term extension must be passed on or before that date in order to avoid a government shutdown.

**Administration Activity**

**Administration Releases Final Rule and Proposed Rule on Healthcare Transparency**

On November 15, the Administration announced the release of two transparency regulations:

1. The “CY2020 Hospital Outpatient Prospective Payment System (HOPPS) Policy Changes: Hospital Price Transparency Requirements” is a final rule that requires, effective 1/1/21, all hospitals in the U.S. to make their standard charges for all items and services available to the public in a machine-readable format. The rule also requires hospitals to make public, in a consumer-friendly manner, discounted and payer-specific negotiated prices for a range of 300 “shoppable services” (i.e. those that can be scheduled by the consumer in advance). The American Hospital Association immediately promised to sue the Administration over the rule, asserting that the Administration lacks the authority, and that the rule violates their First Amendment rights and forces the disclosure of protected trade secrets.

2. The “Transparency in Coverage” proposed rule would require, one year after the rule’s finalization, all non-grandfathered group health insurance plans and all health insurance issuers offering non-
grandfathered health insurance coverage in the individual and group markets to establish an online tool that will allow enrollees to get estimates of their personalized out-of-pocket costs for all covered healthcare items and services so that consumers can compare costs and shop among different providers prior to the receipt of care. In addition, the proposed rule would require health insurance plans to make available to the public two machine-readable files with all of their in-network negotiated rates with providers, as well as historical payments of allowed amounts to out-of-network providers. Such files would be required to be updated monthly. Comments on the proposed rule are due 60 days after its publication in the Federal Register.

Democratic Presidential Primary
Democratic Field Shrinks, Re-Expands as Candidates Continue to Refine Health Care Platforms
The fifth Democratic presidential debate took place on November 15 in Atlanta, Georgia, with 10 candidates having met the polling- and fundraising-based criteria the DNC requires to take part: Former Vice President and Sen. Joe Biden (DE), Sen. Bernie Sanders (VT), Sen. Elizabeth Warren (MA), Sen. Kamala Harris (CA), Sen. Cory Booker (NJ), Sen. Amy Klobuchar (MN), South Bend, IN Mayor Pete Buttigieg, entrepreneur Andrew Yang (NY), Rep. Tulsi Gabbard (HI) and philanthropist Tom Steyer (CA). Unlike in the first four debates, where health care often took center stage, the candidates’ health care platforms took a back seat to their positions on topics like the ongoing impeachment proceedings against President Trump, foreign policy, climate change and economic inequality. All ten of the participating candidates have publicly voiced their support, either during debates or in other forums, for at least an impeachment inquiry, while a handful of leading candidates (Biden, Sanders, Warren, Harris and Buttigieg) have outright called for Trump’s impeachment.

Though health care was not the predominant topic of conversation in November’s debate, some candidates’ health care platforms came into clearer focus throughout the month. Sen. Warren released details on how she would propose paying for her brand of Medicare-for-All, namely, through a mix of new and increased taxes on the wealthy, cuts to provider reimbursement, cuts to military spending, new payments from employers no longer tasked with procuring health coverage for employees, and immigration reform designed to boost tax revenue. She also expanded on her proposed timeline for a phased rollout, committing to pursuing legislation to implement “full” Medicare-for-All no later than her third year in office.

In addition, Sen. Booker released a new drug pricing bill, the “Prescription Drug Affordability and Access Act,” which would create an independent agency—modeled after Canada’s Patented Medicine Prices Review Board—to review drug prices and “(determine) appropriate prices,” with noncompliance (i.e. a company pricing a reviewed product higher than the agency’s recommended price) triggering HHS to permit competitors to produce generic versions of the drug in question. The bill, co-sponsored by Sens. Sanders and Harris, also contains transparency requirements relating to R&D costs, to a drug’s overseas prices, to the prices of comparable products, and to any public funding that went into its development.

Of additional note, former Rep. Beto O’Rourke (TX) dropped out of the race in November, while former New York City Mayor Michael Bloomberg and former Massachusetts Governor Deval Patrick entered it. This leaves 18 Democratic candidates in contention for the party’s nomination.