New Year, New AIM

By Cary Perry, MD
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The new year brings many things—a fresh start with resolutions and plans galore. This can mean personal goals, as well as more broad-ranging goals. The new year also brings a new legislative session at the Capitol in Atlanta. In perusing the upcoming agenda, as well as a list of last year’s medically-related items in the latest Medical Association of Georgia Journal (January 2018), it is astounding to see the depth and breadth, as well as the sheer number of bills proposed that have some relationship to medicine—its practice, its practitioners, the finances, and health care in general. I would venture to say that the majority of the bills from last year’s docket quite honestly related to the financial side of health care, particularly as it pertains to hospitals and insurers. Those pieces of legislation, while important and affecting us all eventually, may not have what we all deem to be direct impact on patient care and health, the one thing that drives us all to get out of bed each day and show up and serve. Once you drill down and find those rare proposals, it is always comforting to know that our best interests are well-represented at the Capitol in the capable hands of Skin Edge and Daniel Thompson. Andy Toledo has done and will continue to do an admirable job of keeping the Board and the membership up to date on crucial proposals that deserve our attention and support. I would continue to urge every member to pay attention to e-mails and messages throughout the session that may call on you to contact your local representatives. This, of course, extends to the broader national forum, as well. There is no doubt in my mind that a strong, collective, well-organized voice comprised of physicians gets attention. Stay informed and make sure your voice is heard. With that being said, I think it remains important to remember that the biggest changes often come from efforts made at the grassroots level and by workers on the ground. In the case of providing the best possible care to the women of Georgia, these workers are OB/GYNs, nurses, and midwives.

This is why I want to revisit an article from our August 2017 newsletter entitled “Quality Improvement Initiatives for Maternal Care in Georgia.” This was most of our membership’s initial introduction to the Alliance for Innovation on Maternal Health (AIM). AIM is “a national partnership of provider, public health and advocacy organizations... that aligns national, state and hospital level efforts to improve maternal health and safety.” The ultimate goal is to reduce severe maternal morbidity and mortality in the very short term. This is accomplished by the implementation of safety bundles within member hospitals. Metrics are in place to assess for measuring adoption of these safety bundles, as well as maternal outcomes in those hospitals. De-identified data is collected and benchmarked with other similar hospitals within states and networks and reported back to those participating hospitals and states. Members are then able to utilize this data to identify successes and weaknesses with their personal implementation of the safety bundles. These safety bundles are standardized, evidence-informed processes to reduce variation in hospital maternal care. They are developed by multidisciplinary work groups of experts in the field from the various...
Beginning January 1, 2018, physicians in Georgia are now required to complete at least 3 hours of AMA AOA/PRA Category 1 CME designated to address controlled substance prescribing practices as a requirement to obtain licensure to practice medicine in Georgia, under Georgia rule 360-15-.01. Through the partnership with the GOGS, The Doctors Company will grant access to this CME free of charge. You will receive an email from The Doctors Company with a link that will enable access to their web-based on-demand course catalog. The Doctors Company catalog contains three 1-hour courses of the required content, including instruction on controlled substance prescribing guidelines, recognizing the signs of abuse or misuse of controlled substances, and controlled substance prescribing for chronic pain management. You will receive a CME certificate for 1 hour for each of the three 1-hour courses you complete.

The course can be accessed at https://thedoctormeet.com/ and is 50000290445. If you have questions, contact educationsupport@thedoctorme.com or call (800) 421-2368.

Supreme Court Decisions in 2017 That Affected Your Practice

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by Steven R. Smith, MD, JD and Joseph S. Sanfilippo, MD, MBA

Despite being short-handed (there were only 8 justices for most of the Term), the United States Supreme Court decided a number of important cases during its most recent Term, which concluded on June 27, 2017. Among the 69 cases, several are of particular interest to OB Gyns.

1. Arbitration in health care
In Kindred Nursing Centers v Clark, the Court decided an important case regarding arbitration in health care. At stake, the families of 2 people who died after being in a long-term care facility filed lawsuits against the facility. Because arbitration agreements are becoming ubiquitous and rigorously enforced by federal courts, arbitration is bound to have an important function in health care.

The case suggests both a warning and an opportunity for health care providers. The warning is that arbitration clauses will be enforced, thoughtlessly entering into arbitration for future disputes may be dangerous. Among other things, the decision of arbitrators is essentially unreviewable. Appellate courts review the decisions of lower courts, but there is no such review in arbitration. Furthermore, arbitration may be stacked for favor of commercial entities that often use arbitrators.

The opportunity for health care providers lies in that it may be possible to include arbitration clauses in agreements with patients. This should be considered only after obtaining legal advice. The agreements should, for example, be consistent with the obligations to patients (in the case of the Kentucky facility, it made clear that accepting the arbitration agreement was not necessary in order to receive care or be admitted to the facility). Because arbitration agreements are becoming ubiquitous and rigorously enforced by federal courts, arbitration is bound to have an important function in health care.

2. Pharmaceuticals and biosimilars
Pharmacists play an important role in health care, as an estimated 10% of 2016 sales was biologics. The case of Sandzor v Amgen involved biosimilar pharmaceuticals, essentially the generics of biologic drugs.

At stake, while biologics hold great promise in medicine, they are generally very expensive. Just as with generics, brand-name companies (generally referred to as “reference” biologics) want to keep biosimilars off the market for as long as possible, thereby extending the advantages of monopolistic pricing. This term the Supreme Court considered the statutory rules for licensing biosimilar drugs.

Final ruling. The Court’s decision will allow biosimilar companies to speed up the licensing process by at least 180 days. This is a modest win for patients and their physicians, but the legal issues around biosimilars will need additional attention.

Class action suits
In another case, the Court made it more difficult to file class action suits against pharmaceutical companies in state courts. Although this is a fairly technical decision, it is likely to have a significant impact in pharmaceutical liability by limiting class actions.

3. The travel ban
The American College of Obstetricians and Gynecologists joined other medical organizations in an amicus brief in support of Trump’s travel ban.
Care and Premier are two health care this means are that major hospitals clinical meeting when Dr. Melissa practice and believe in. difficult to buy into what you already be quite painless and simple. It isn't best clinical practice. The process of have adopted through our years of Preeclampsia. If I had to summarize has chosen to focus on Obstetric applicable in all of our day-to-day hospitals “must be able to display and education. To join, states and (who had completed their sentences) to use social media sites that “permit minor children to become members and create and maintain personal page.” At stake. In Packingham v North Carolina, for example, made it a felony for sex offenders (who had completed their sentences) to use American colleges, workers who have accepted US businesses or institutions (such as students who have been admitted to American colleges, workers who have accepted US employment, or lecturers invited to address American audiences).6 Following the Term, the Administration issued a different travel ban, so the issue was taken off the Court’s calendar for the moment. There undoubtedly will be additional chapters to come. 4. Birth certificates and same-sex marriage In Pavan v Smith, the legal question concerned whether married same-sex couples may have both parents listed on the birth certificate of children born during the marriage. Two same-sex couples conceived children through anonymous sperm donation and gave birth in Arkansas. The Department of Health in Arkansas issued birth certificates listing the mother’s name, but refused to list the father’s name, even though the couple was married. At stake. The couples brought suit claiming a constitutional right to have both parents listed. In particular, they noted that under Arkansas law, the wife of a same-sex couple who had the child should be the mother. When the woman is married, the husband’s name is “entered on the certificate as the father of the child.” The same-sex parents argued that a 2015 decision of the Supreme Court held that the Constitution requires states to recognize same-sex marriages, made it clear that same-sex couples should have the benefits of marriage. Eventually the case wound its way to the Supreme Court.

At stake. The brief argued that the University ordinarily lists the names of both husband and wife on such certificates, then same-sex couples are entitled to have birth certificates listing both parents. The Court noted that laws are unconstitutional if they treat same-sex couples differently than opposite-sex couples. Based on this principle, the Court held that parental birth certificate registration is part of the “constellations of benefits” linked to marriage that the Constitution affords same-sex couples. This ruling applies as a matter of constitutional right in all states. 5. Sexual offenders and social media States struggle to protect children from convicted sex offenders. North Carolina, for example, made it a felony for sex offenders (who had completed their sentences) to use social media sites that “permit minor children to become members and create and maintain personal pages.” At stake. In Packingham v North Carolina, the Court was asked to decide whether this statute violates the First Amendment (free speech) rights of sex offenders.6 Final ruling. The Court held that the North Carolina limitation on sex offenders’ use of social media was too broad. It noted the wide range of political, employment, professional, and religious websites that are off limits to sex offenders under the statute—hardly narrowly tailored. It suggested, however, that it probably would be constitutional for a state to prohibit sex offenders “from engaging in conduct that often presages a sexual crime, like contacting a minor or using social media to gather information about a minor.”7 Final ruling. The Court held that the North Carolina limitation on sex offenders’ use of social media was too broad. It noted the wide range of political, employment, professional, and religious websites that are off limits to sex offenders under the statute—hardly narrowly tailored. It suggested, however, that it probably would be constitutional for a state to prohibit sex offenders “from engaging in conduct that often presages a sexual crime, like contacting a minor or using social media to gather information about a minor.”7 Final ruling. The Court held that the North Carolina limitation on sex offenders’ use of social media was too broad. It noted the wide range of political, employment, professional, and religious websites that are off limits to sex offenders under the statute—hardly narrowly tailored. It suggested, however, that it probably would be constitutional for a state to prohibit sex offenders “from engaging in conduct that often presages a sexual crime, like contacting a minor or using social media to gather information about a minor.”7 Final ruling. The Court held that the North Carolina limitation on sex offenders’ use of social media was too broad. It noted the wide range of political, employment, professional, and religious websites that are off limits to sex offenders under the statute—hardly narrowly tailored. It suggested, however, that it probably would be constitutional for a state to prohibit sex offenders “from engaging in conduct that often presages a sexual crime, like contacting a minor or using social media to gather information about a minor.”7 Final ruling. The Court held that the North Carolina limitation on sex offenders’ use of social media was too broad. It noted the wide range of political, employment, professional, and religious websites that are off limits to sex offenders under the statute—hardly narrowly tailored. It suggested, however, that it probably would be constitutional for a state to prohibit sex offenders “from engaging in conduct that often presages a sexual crime, like contacting a minor or using social media to gather information about a minor.”7 Final ruling. The Court held that the North Carolina limitation on sex offenders’ use of social media was too broad. It noted the wide range of political, employment, professional, and religious websites that are off limits to sex offenders under the statute—hardly narrowly tailored. It suggested, however, that it probably would be constitutional for a state to prohibit sex offenders “from engaging in conduct that often presages a sexual crime, like contacting a minor or using social media to gather information about a minor.”7
Legislative Day 2018

This year’s Primary Care Physicians Coalition (PC2) Legislative Day was a huge success! Thank you to everyone who attended and for the opportunity to host the event. A record 230 physicians from the Georgia Chapter – American Academy of Pediatrics, Georgia Academy of Family Physicians, Georgia Chapter – American College of Physicians, Georgia OB/GYN Society, and Georgia Osteopathic Medical Association descended upon the capitol to network with colleagues, hear from state leaders and meet with their legislators on the issues that are most concerning for the practice of primary care in Georgia. For OB/GYNs, we continue to advocate for increased state funding for OB/GYN residency slots and funding to prevent maternal deaths. The group was fortunate this year to hear from Governor Nathan Deal, who is in his last year as governor. Governor Deal thanked the group for the work we do every day taking care of patients and encouraged those who are in residency to stay in Georgia and consider practicing in rural areas. Speaking on behalf of the group, I thanked the Governor for his support in increasing Medicaid reimbursements for primary care physicians for three straight years, increasing state funding to support OB/GYN resident slots, and for his efforts to repair the rural healthcare infrastructure.

In addition, we had a record number of first-time attendees and residents! This is very exciting for the future of primary care in Georgia. Please, continue to reach out to your elected officials and cultivate those relationships. Invite them for coffee or invite them to come by your office and introduce them to your practice and the challenges you face. Working in an industry that is the subject of many government regulations from how many beds can be in a unit to how and how much we are paid, it is incumbent upon you – the OB/GYN – to advocate for your profession and the patients you treat.

If you do not know who your elected official is, visit https://openstates.org/ and input your home address on the right side. Finally, if you have not already done so, please consider a donation to GynPAC. It can be included in the cost of your annual membership fee to the society. If you have any questions, please contact the society main office.

Please be on the lookout for the date for next year’s PC2 Legislative Day at the Capitol!
When the opioid epidemic hit the news—not just in scientific journals but in the popular media as well—it spurred Congress and state legislatures to offer public healthcare policy solutions. This has resulted in increased funding for treatment, more regulations for prescribing opioids, measures to increase the availability of opioid antagonists, and a reduction in liability for the administration of opioid antagonists.

Celebrity Tragedy and National Statistics

In 2016, the autopsy of pop music legend Prince found that the singer died from a “self-administered” dose of the opioid fentanyl. Prince’s tragic demise was only one of many celebrity deaths attributed to opioid-related causes. Celebrity deaths brought the dangers of opioids to the public’s attention, and statistics for the general population support the perception of an opioid addiction epidemic. Centers for Disease Control (CDC) Director Dr. Tom Frieden noted: “We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.”

Between the media attention and the preponderance of evidence that opioid usage had become a major public health problem in America, legislators were spurred to address the problem.

Legislation and Administrative Action

Lawmakers typically attempt to solve problems in two ways: (1) providing funding for programs, and (2) enacting regulations through legislation. As an indicator of the level of concern of U.S. lawmakers, the usually gridlocked Republican Congress and Democratic President Barack Obama united to address the issue. On December 13, 2016, both houses of Congress and the president worked together to approve legislation that granted $1 billion to state opioid abuse programs. This was a sharp increase in funding from earlier in the year and from previous years. (The Senate passed the law by a vote of 94–5, and the House of Representatives passed the law by a vote 355–77.)

On October 26, 2017, President Donald Trump declared the opioid addiction crisis a public health emergency via the Public Health Service Act, though minimal new funding accompanied the declaration. The White House and Congress will need to work together to increase the depleted Public Health Emergency Fund.

Two states—Colorado and Indiana—have since created funding for opioid treatment pilot programs. The Maine legislature overrode its governor’s veto to ensure access to opioid addiction treatment. Some states that passed a Medicaid program for those with insurance and New Jersey have enacted laws requiring healthcare insurers to provide coverage for opioid addiction treatment. Legislators have also passed laws regulating the prescribing of opioids.

Required Physicians to Check Prescription Databases

Prescription drug databases, originally intended to be used by law enforcement, have been widened to allow healthcare providers and prescribers to review a patient’s prescription history for signs of overprescribing or addiction. Every U.S. state with the exception of Missouri has a prescription monitoring database.

Some states have been even further. By 2016, 18 states had passed legislation requiring medical professionals to consult a state database: California, Connecticut, Kentucky, Maine, Maryland, Massachusetts, Nevada, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Texas, West Virginia, and Wisconsin.

State laws and regulations mandating prescribers to query the database vary as to requirements, but in general, most require the prescriber to check: (1) before initially prescribing a controlled substance to a patient in an opioid treatment program, (2) in workers’ compensation cases, and (3) prior to initially prescribing or dispensing an opioid analog or benzodiazepine in any setting.

Most often, the penalty for prescribers for failure to check the database is referral to the department or board that enforces violation of professional standards.

Opioid Antagonist Access Laws and Good Samaritan Protections

Legislators have also sought to decrease deaths from prescription opioid abuse by increasing access to opioid antagonists. These drugs have

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How Lawmakers Are Tackling the Opioid Epidemic (continued from page 9)

no abuse potential and counteract the life-threatening effects of an overdose, allowing the victim to breathe normally once administered.

Previously, access to these lifesaving medications was limited because a doctor-patient relationship needed to exist for a prescription to be issued. This requirement was ineffective because family and friends are often in the best place to administer an antagonist during an overdose, but they did not have access to a prescription.

In 2001, New Mexico became the first state to enact legislation increasing access to opioid antagonists. Over the past 15 years, 47 states and the District of Columbia have passed similar laws. In the 2017 legislative year, Montana, North Carolina, Nevada, Tennessee, Texas, Virginia, Wisconsin, and West Virginia enacted laws making opioid antagonists more available.

In conjunction with increasing access to opioid antagonists, many states have passed Good Samaritan laws to limit liability for healthcare professionals and “laypersons” for administering opioid antagonist medications. For immunity to apply, laws typically require that a person must have a reasonable belief that someone is experiencing an overdose emergency, must remain on scene until help arrives, and must cooperate with emergency personnel. For healthcare personnel, immunity will usually apply unless there is gross negligence in the administration of the opioid antagonist.

Good Samaritan laws for the administration of opioid antagonists have been passed in 37 states and the District of Columbia. The 13 states that have yet to pass opioid antagonist Good Samaritan laws are Arizona, Idaho, Iowa, Kansas, Maine, Missouri, Montana, Nebraska, Oklahoma, South Carolina, South Dakota, Texas, and Wyoming.

Florida lawmakers have had proposed legislation, Senate Bill 458, during the 2018 legislative session. If enacted in its current form, this bill will:
• Limit a controlled opioid prescription to a 7-day supply.
• Limit refill or subsequent controlled opioid prescription to a 30-day supply.
• Provide exceptions to supply limits for certain patients.
• Require a prescriber to access a patient’s drug history in the prescription drug monitoring program’s database before prescribing the drug, and at least every 90 days thereafter for continuing treatment.
• Require a healthcare practitioner to complete a continuing education course as a condition of initial licensure and biennial licensure renewal. In 2017, Florida House Bill 477 added synthetic opioids to the list of controlled substances.

Georgia’s Response
On May 4, 2017, Governor Nathan Deal signed three laws into effect to address the opioid crisis gripping Georgia. SB 121 exempts Naloxone, the emergency drug used to reverse opioid overdoses, from the dangerous drug list when it is used for drug overdose prevention and supplied by a dispenser for various types of rescue kits. This legislation also codifies the executive orders put in place by Deal in 2016. SB 88 requires the Department of Community Health to create minimum standards and quality of services for narcotic treatment programs seeking licensure in Georgia. Provision of HB 249 include moving the Prescription Drug Monitoring Program from the Georgia Drugs and Narcotics Agency to the Department of Public Health. The Georgia OBGyn Society has partnered with The Doctors Company to offer free CME to physicians that will satisfy the requirements for physician education passed by the Georgia Composite Medical Board in 2017.

In the 2018 General Assembly, SB352 by Sen. Unterman is an omnibus bill containing 3 sections aimed at addressing the ongoing opioid crisis. Section 1 imposes broad restrictions on health care providers making, soliciting or receiving any type of remuneration or kickback for patient referrals. This “anti-kickback” bill is similar in nature to the federal Anti-Kickback Statute and contains criminal penalties for any violation.

Section 2 requires the Governor to appoint a director of Substance Abuse, Addiction, and Related Disorders. It also establishes a Commission on Substance Abuse and Recovery charged with creating a “coordinated and unified effort among state and local agencies to confront the state-wide addiction and substance abuse crisis.”

Section 3 expands the definition of insurance fraud to include the billing of multi-substance drug tests separately for each type of drug tested. SB 352 is being considered by the General Assembly.

Conclusion
The legislative response to the opioid epidemic includes expanding healthcare providers’ ability to access databases that track opioid prescriptions. Lawmakers are also working to ensure easier access to opioid antagonists and immunity to those who administer opioid antagonists. Legislators are also providing more public funding for existing programs for treatment of opioid-addicted patients.

At this point, there is insufficient data to evaluate the effectiveness of the recently passed legislation, but lawmakers and public health advocates hope to see a decline in opioid-related deaths when data becomes available.