AMA: High court ruling an egregious allowance of government intrusion into medicine

According to a statement from AMA President Jack Resneck Jr., MD, “The American Medical Association is deeply disturbed by the U.S. Supreme Court’s decision to overturn nearly a half century of precedent protecting patients' right to critical reproductive health care—representing an egregious allowance of government intrusion into the medical examination room, a direct attack on the practice of medicine and the patient-physician relationship, and a brazen violation of patients’ rights to evidence-based reproductive health services. States that end legal abortion will not end abortion—they will end safe abortion, risking devastating consequences, including patients' lives.

“Today’s opinion shifting reproductive health decision-making to lawmakers opens a deep political rift between states over access to reproductive health services that places sound medical practice and the health of patients at risk. State restrictions that intrude on the practice of medicine and interfere with the patient-physician relationship leave millions with little or no access to reproductive health services while criminalizing medical care.

“Access to legal reproductive care will be limited to those with the sufficient resources, circumstances, and financial means to do so—exacerbating health inequities by placing the heaviest burden on patients from Black, Latinx, Indigenous, low-income, rural, and other historically disadvantaged communities who already face numerous structural and systemic barriers to accessing health care.

“In alignment with our long-held position that the early termination of a pregnancy is a medical matter between the patient and physician, subject only to the physician’s clinical judgment and the patient's informed consent, the AMA condemns the high court’s interpretation in this case. We will always have physicians’ backs and defend the practice of medicine, we will fight to protect the patient-physician relationship, and we will oppose any law or regulation that compromises or criminalizes patient access to safe, evidence-based medical care, including abortion. As the health of millions of patients hangs in the balance, this is a fight we will not give up.”
AMA applauds Senate passage of bipartisan firearm safety legislation

According to a statement yesterday from AMA President Jack Resneck Jr., MD, “For the first time in a generation, we see that bipartisanship is possible on the issue of firearm safety, that compromise can produce meaningful results, and that Congress can come together in response to what the AMA considers a public health crisis of firearm violence. We applaud the Senate and the bipartisan group of senators who negotiated and wrote the Bipartisan Safer Communities Act, and we urge the House of Representatives to act quickly and pass this legislation. This package will save lives.

“But the journey to reduce firearm violence must not end with this bill. Physicians across the country see up close and every day the impact these weapons of war have on the human body. We see it in our emergency departments, in our trauma centers, and, yes, in our morgues. For decades, the AMA has built robust policy to prevent firearm violence – both the everyday type that is so common in our communities it often no longer receives a mention on the local news, and the type that grabs national attention, forces us to reflect, and makes millions march.

“In 2020, 45,222 Americans were killed by firearms. They were our friends and neighbors, our parents, our children, our teachers, and our fellow parishioners. Much more can and should be done, including research to inform the implementation of evidence-based policies and programs to prevent firearm violence in the first place. The AMA remains steadfastly committed to common-sense solutions to save lives.”

The House passed the legislation today, and it now heads to the President for signature. Find more information on the AMA’s advocacy against firearm violence.

New AMA policies and strategies to prevent firearm violence

“Gun violence is a plague on our nation. It’s a public health crisis, and much of it is preventable,” said then-AMA President Gerald E. Harmon, MD, in remarks to the House of Delegates at the 2022 AMA Annual Meeting. “This cannot be our new normal. Gun violence is out of control. Enough is enough.”

In a statement, Dr. Harmon also applauded a recent bipartisan deal to address gun violence but emphasized that there must be additional, significant steps taken to combat this public health crisis.

Further, Bobby Mukkamala, MD, addressed the AMA House of Delegates as chair of the Board of Trustees to detail the AMA’s emphatic commitment to halting gun violence. He said, “We are
continuing to push Congress to double the funding for gun violence research. We will push for the passage of the bipartisan Senate framework on preventing gun violence. We will push for a stronger action by Congress and the administration. This includes the provisions of the AMA-supported Protecting Our Kids Act.”

In addition, Dr. Mukkamala outlined ways in which the AMA will continue to address firearm violence:

- Encouraging intervention by physicians and nurses when patients demonstrate risk factors for gun violence.
- Amplifying AMA work with other organizations related to firearm safety and gun violence prevention.
- Reaching out to law enforcement and educators to explore how collaborative progress can be made.

On June 21, AMA President Jack Resneck Jr., MD, participated in a press conference with Giffords, the gun violence prevention organization led by former Congresswoman Gabrielle Giffords, and other members of the medical community to call for Congressional action on our nation’s gun violence crisis. With ongoing discussions in the Senate, this is a crucial time in the debate.

Alongside these ongoing advocacy efforts, the AMA House of Delegates also adopted a number of new policies aimed at preventing firearm violence, including:

- Ensuring active-shooter and live-crisis drills consider the mental health of children: The AMA encourages these drills to be conducted in an evidence-based and trauma-informed way that takes children’s physical and mental wellness into account.
- Regulating ghost guns: The AMA calls on state legislatures and Congress to subject these weapons to the same regulations and licensing requirements as traditional firearms.
- Advocating for warning labels on ammunition packages: The AMA will support legislation requiring that packaging for any firearm ammunition produced in, sold in or exported from the United States carry a boxed warning.

These policies add to the AMA’s already numerous policy recommendations to reduce firearm trauma, injury and death that have been developed over the past two decades.

According to a recent statement from Dr. Resneck, the AMA is deeply disappointed with the U.S. Supreme Court’s harmful and disturbing decision to strike down a New York State measure regulating concealed carry licenses for handguns as an appropriate and constitutional response by state government officials to the scourge of firearm violence in their local communities.

Firearm violence is a public health crisis, and easier access to weapons and fewer restrictions on who can carry them—and where they can be carried—are dangerous steps in the wrong direction. The
AMA will remain a strong advocate for firearm regulations as an essential element of effective public-safety policy. Learn more.

**Bipartisan House bill advances prior authorization Gold Card policies**

Prior authorization, or the practice of insurance companies reviewing and potentially denying coverage of medical services and pharmaceuticals prior to treatment, remains a principal frustration for physicians and jeopardizes patient care. Representatives Michael Burgess, MD (R-TX) and Vicente Gonzalez (D-TX) took an important step in helping to minimize the burden of this particular utilization management policy following introduction of the “Getting Over Lengthy Delays in Care as Required by Doctors” (GOLD CARD) Act of 2022.

This bipartisan bill exempts physicians from Medicare Advantage (MA) plan precertification requirements so long as 90% of the physicians’ prior authorization requests were approved in the preceding 12 months. MA plan-issued gold cards are applicable only to items and services (excluding drugs) and remain in effect for at least a year. The legislation is based on a similar law enacted in Texas that took effect in 2021.

Following direct advocacy from the AMA, the GOLD CARD Act also establishes numerous processes to ensure that MA plans cannot inappropriately revoke this exception to prior authorization practices. Although permitted to rescind the exemption, MA plans must demonstrate that less than 90% of claims submitted during a 90-day plan period would not have received prior authorization. This 90-day lookback period must be extended until at least 10 claims are ultimately provided. Services that are initially denied and pending appeal for at least 30-days are required to be considered “approved” with respect to the 90% threshold.

The bill also explicitly excludes services impacted by a change in coverage determinations that were submitted during the 90-day lookback period. Most importantly, MA plan physicians who review the potential gold card rescission are required to be actively engaged in the practice of medicine in the same or similar specialty as the physician under review, have knowledge about the specific service in question and possess a current, nonrestricted license in the same state as the furnishing physician. Physicians who possess the gold card can also appeal any attempt to rescind the exemption.

AMA data (PDF) continues to illustrate the negative impact of prior authorization on physicians and patients. In fact, 34% of respondents to a 2021 AMA survey reported that prior authorization led to a serious adverse event, such as hospitalization, disability, permanent bodily damage or death, for a patient in their care. The 2021 survey also highlights that 93% of physicians reported care delays associated with prior authorization and 82% said these requirements can at least sometimes lead to
patients abandoning treatments.

In addition, research from the federal government further demonstrates that prior authorization leads to delays in patient care and inappropriate denials of medically necessary services. A 2018 report (PDF) from the Department of Health and Human Services (HHS) Office of Inspector General (OIG) concluded that, between 2014 and 2016, MA plans overturned 75% of their own prior authorization and payment denials when appealed by providers and beneficiaries. An April 2022 HHS OIG report (PDF) found that 13% of prior authorization requests denied by MA plans met Medicare coverage rules and 18% of payment request denials met Medicare and MA billing rules.

AMA commends Reps. Burgess and Gonzalez for introducing H.R. 7995 as reforming prior authorization is a key pillar of the AMA’s recently launched “Recovery Plan for America’s Physicians.”

**AMA and ACOG join to support continued access to mifepristone**

Consistent with policy adopted at the recent House of Delegates meeting, the AMA and the American College of Obstetricians and Gynecologists (ACOG) joined on two June 21 letters to the White House (PDF) and Food and Drug Administration (FDA) (PDF) to support continued unrestricted access to mifepristone. Access to mifepristone is increasingly at issue given its use to terminate pregnancies in home settings. The drug is also widely used for management and treatment of early pregnancy loss (miscarriage, spontaneous abortions, missed abortions). The AMA and ACOG are encouraging the administration to remove or revise the drug’s current risk evaluation and mitigation strategies (REMS) to remove potential barriers to access to mifepristone and are also supporting the authority of FDA approval to preempt state laws that further restrict access to the drug.

In Dec. 2021, FDA removed a requirement included in the drug’s REMS that necessitated dispensing of the drug by a physician and required the first dose to be taken in the presence of the prescribing physician. However, several states have moved to further restrict mifepristone access and have continued in-person dispensing requirements, with 26 states limiting telemedicine access to the drug. Mifepristone manufacturers are currently pursuing legal action to challenge these continued restrictions in states that enact them. Those legal actions could have far-reaching implications, not only impacting access to abortion care but possibly deciding whether states can place additional dispensing restrictions on FDA-approved drug products that are not included in the product approval and labeling.

Additional actions at the state level restricting access to mifepristone will be closely watched given the Supreme Court ruling in Dobbs v. Jackson Women’s Health Organization, which will have severe impacts on access to abortion care in many states.
AMA, leading health care organizations push for extended ACA premium tax credits

The AMA and other leading health care organizations called on Congress in a recent letter (PDF) to extend the expanded Affordable Care Act (ACA) health care premium tax credits. The groups represent tens of millions of American patients, consumers, physicians, nurses, community health centers and health insurance providers.

The organizations expressed their concerns with the “cost and coverage ramifications that Congressional inaction would mean to the populations [they] serve,” stating that “failure to pass legislation extending the American Rescue Plan’s ACA premium tax credits will mean that enrollees’ premiums will increase by double digit levels.” The consequences of these increases will lead to at least three million Americans losing their health insurance and will consequently result in inaccessible and unaffordable health care for consumers. There will be similar financial burdens for health care providers, who will experience increases in uncompensated care.

The groups state that “Not only will Congressional inaction result in major cost and coverage consequences for 2023, but the downstream effect will likely further drive-up costs and decrease coverage in 2024.” However, this destabilized insurance market can be avoided through policy development and Congressional action to extend coverage.

CMS to hold two webinars on the No Surprises Act

The AMA has been working with the Centers for Medicare & Medicaid Services (CMS) to encourage more physician outreach and education on the No Surprises Act (NSA) implementation. As part of this effort, CMS is going to be hosting additional webinars on specific NSA topics in the coming weeks, the first two topics being the law’s Good Faith Estimate provisions and surprise billing provisions.

- Tuesday, June 28, 12-1 p.m. Eastern: Good Faith Estimate
- Wednesday, July 13, 1-2 p.m. Eastern: Surprise billing, notice and consent, and enforcement

CMS has stated that they plan to spend a significant portion of each webinar addressing questions from physicians and medical societies. The AMA has been told they will take live questions through the Q&A function but they would also like to answer pre-submitted questions and address real-life scenarios that are brought to them before the webinar. To that end, the AMA would like to collect as many questions as possible before the webinar and provide them to CMS so they can be prepared with answers.
Please send questions you and your physician members may have about the below NSA requirements to Emily Carroll (emily.carroll@ama-assn.org) as soon as possible and the AMA will communicate them to CMS:

- The Good Faith Estimate requirements for uninsured or self-pay patients
- Surprise billing prohibitions
- Notice and Consent requirements
- NSA enforcement requirements
- The payment process under the NSA, including the initial payment, open negotiations and Independent Dispute Resolution process (to be addressed in a yet-to-be-scheduled future webinar and in other educational/advocacy efforts)

Follow the steps below to register for the webinars:

1. Create a REGTAP account if needed. Please see instructions at the following link: https://regtap.cms.gov/reg_tips.php#UserAccountRegistration.
2. Log into REGTAP (https://regtap.cms.gov) and, after completing login, enter the following registration weblinks into your browser to reach the REGTAP registration page for June 28 and for July 13.
3. Select ‘Submit’ on the registration event page after reviewing and accepting the attendance and waitlist policy.
4. You will receive an email confirmation following registration from autoresponder@regtap.info.
5. The registration deadline is 24 hours before each webinar.

For more information, view related toolkits on these new requirements.

**FTC ramps up focus on pharmacy benefit managers**

The month of June has seen a significant focus from the Federal Trade Commission (FTC) on the role of pharmacy benefit managers (PBMs) in prescription drug pricing and access. On June 7, the FTC announced that, after a unanimous vote from its commissioners, it will be launching a formal inquiry into the role of PBMs in the pharmaceutical marketplace, requiring the six largest to provide information and records regarding their business practices. The inquiry will scrutinize the impact of these vertically integrated PBMs on access to and affordability of prescription drugs, with a focus on:

- Fees and clawbacks charged to unaffiliated pharmacies
- Methods to steer patients toward PBM-owned pharmacies
- Potentially unfair audits of independent pharmacies
- Complicated and opaque methods to determine pharmacy reimbursement

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The prevalence of prior authorizations and other administrative restrictions
The use of specialty drug lists and surrounding specialty drug policies
The impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients

Following the announcement, the agency partnered with the Department of Justice for a two-day public workshop on antitrust enforcement in the pharmaceutical industry, shedding additional light on anticompetitive behavior by major industry stakeholders. Additionally, the FTC on June 16 released a new policy statement on illegal rebate arrangements by PBMs that result in exclusion of lower cost drug products from formularies and generate larger rebates and fees for PBMs that are not shared with patients. The FTC noted that it anticipates ramping up enforcement on these rebate/fee arrangements and outlined a number of tools that it can use to do so.

In addition to the recent FTC action to increase scrutiny on PBM practices, it has been widely reported that members of the House Committee on Education and Labor have requested the Government Accountability Office to conduct a study on how PBMs provide services to commercial health plans, how they are reimbursed and how PBM formularies and rebate arrangements affect commercial drug spending.

More articles in this issue

- June 24, 2022: Advocacy Update spotlight on the 2022 AMA Annual Meeting
- June 24, 2022: State Advocacy Update